Otodynamics
Audiology Systems

Otoport Lite

User Manual

Otoport Lite

Issue 3

Otoport Lite

Issue C3 : January 2013
Otoport Lite v3.24.1.0 onwards
Doc Ref: MANOLC-03

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1 Introduction

1.0.a The Otoport provides high quality OAE measurement features in a compact, handheld format. Different models are available to perform either TEOAE or DPOAE tests.

1.0.b The Otoport is simple to use and with powerful measurement features performs an automatic analysis of cochlear status within seconds. Customisable pass criteria control the test's automatic stop mechanism and a clear Pass/Refer indication is provided.

1.0.c The Otoport's impressive list of features includes:

- TEOAE Quickscreen or DPOAE testing
- Ultra fast interactive graphic display
- ILO Gold Standard data format
- Frequency band analysis
- Cell phone type keypad
- 500 record secure database
- Long battery life

1.0.d Options:

- Wireless Printer
- Docking Station
- RFID Scanner
- Barcode Scanner

1.1 General use precautions

1.1.a The Otoport pass criteria are set in the **Configuration** area (see chapter 8 **Configuration**). It is the responsibility of the user to ensure that the pass criteria set meet their requirements.

1.1.b Measuring OAEs requires that the ear is exposed to sound. Whilst the level of this exposure is harmless under normal test conditions, it is not recommended that tests be allowed to continue indefinitely even if there is no result.

1.1.c The Otoport includes 'stop criteria' which will automatically terminate the test when an OAE pass has been achieved or after five minutes.

1.1.d Whilst this limits the sound exposure in a single test, the user is responsible for limiting the number of separate tests performed on the same ear.

1.1.e The Otoport has built in signal analysis proven to distinguish true otoacoustic emissions from artefactal signals. Checks should be performed weekly and before each test session to confirm the system continues to operate effectively (see chapter 11 **Probe checks**).

1.1.f In exceptional circumstances, either an equipment fault or failure to comply fully with the instructions in this manual may result in unreliable test results. Results with total OAE responses greater than 40 dB SPL should be considered highly suspect and should not be relied on.

1.1.g The probe's coupler tubes which carry sound to and from the ear canal are protected from contamination by the disposable tip. The probe should never be inserted into the ear without a disposable tip attached. Doing so risks damage to the ear by the probe body and contamination of the probe by the ear.

1.1.h If contamination occurs the coupler tubes must be replaced (see 13.2 **Changing probe coupler tubes**).

1.1.i Visually inspect the coupler tubes before use. A blocked sound delivery tube may prevent the Otoport from achieving its target stimulation level and so prevent testing. It may also attenuate certain frequencies and limit the number of pass bands. A blocked microphone tube will prevent the Otoport from sensing the stimulus level in the ear and from detecting the OAE. As a result the Otoport may apply a louder than normal sound to the ear.

1.1.j All surfaces of the Otoport may be cleaned with an alcohol based wipe or cloth with antiseptic fluid. Dry the device immediately with tissue.

1.1.k Do not allow liquid to enter the instrument.

1.1.l If additional hygienic protection is required, clear plastic infection control sleeves designed to contain the Otoport during use are available from Otodynamics.

2 Getting started

2.1 Otoport Lite case contents

Note:
Otoport and accessories not shown to scale

2.1.a Take a few moments to familiarise yourself with your Otoport kit:

2.1.b Otoport Lite - handheld OAE instrument

2.1.c UGS TEOAE probe (TE model) or UGD DPOAE probe (DP model)

2.1.d Soft fabric drawstring probe bag

2.1.e Test cavity for probe checks

2.1.f Probe accessories (see chapter 12 for further information):

Probe cable clip

Sample probe coupler tubes

Spare probe body and lid

2.1.g Charger and mains lead or charging cradle

2.1.h PC cable for downloading patient and test data to PC

2.1.i Sample probe tips in compartmented box

2.1.j Otolink software CD

2.1.k Infection control sleeve - transparent, easy-clean cover for optional use with Otoport (shown fitted below right)

2.1.l Documentation pack - including instrument and software manuals, Quickstart and probe use guides

2.2 Optional accessories

2.2.a A range of additional accessories are available from your distributor or from Otodynamics.

2.2.b Otoport docking station - a stable base to hold the Otoport, with connections for printing, charging and downloading to PC (shown with Otoport below right)

2.2.c Otoport printer - a small, portable printer for wired or optional wireless connection

2.2.d Large Otoport case, with additional compartment for printer (shown below left with Otoport kit including printer)

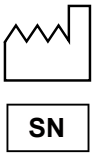
2.3 Controls, indicators and connections

2.4 Scanner and labelling

Barcode/RFID scanner (not included as standard)

Model, serial number, certification, manufacturer details

The Otoport serial number comprises model code (LTC or LDC in this instance), year and month of manufacture (yymm) and unique manufacture ID (xxxx). The complete serial number is therefore LTC/yymmxxxx.



Grip strip

2.5 Initial charge

2.5.a Before using your Otoport for the first time, fully charge the unit. See chapter 15 **Otoport Lite Power** for details.

2.6 Quickstart

2.6.a The Quickstart guide, included as a separate item in your document pack, is shown on the next two pages.

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QUICKSTART
Otoport Lite

Step 1. Setting up your Otoport

1 With the arrow at the front, connect the probe and screw the knurled sleeve until finger tight.

2 Press the button to turn on the Otoport. Confirm within 2 seconds by pressing the button.

3 The startup screen shows the date, time and battery status.

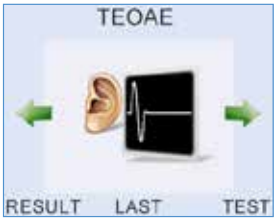
Step 2. Fitting the earpiece

1 Select an appropriate tip.

2 Fit the tip to the earpiece.

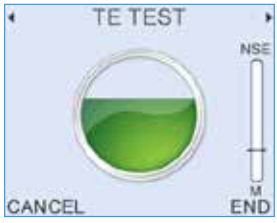
3 Fit the earpiece in the ear canal.

Step 3. Performing a test

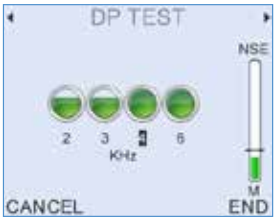


1 To run a **TEST**, press the button.

2 The size of the ear being tested is indicated by the graphic. Press to **START**.



3 During the test the circle fills as OAEs are detected (TE model only). Display depends on test setup.



4 DP tests display a circle for each frequency.

5 The test will auto-stop with the result shown. Select **Save** with the button.

6 Enter the patient details and **Save**.

7 Select the ear tested with the buttons.

8 Select **Save** with the button.

9 After saving you have options to **Retest** the patient, **Print** the result or **Finish** the test.

Step 4. Disconnecting the probe

1 Unscrew the knurled sleeve.

2 Do NOT turn the main probe body.

3 Gently pull out the probe.

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Ref: MOLQ-01
March 2012

2.7 Using the keys and keypad

2.7.1 Control keys

2.7.1.a The keys directly below the screen marked with a square, a diamond or a circle enable you to execute the functions offered on the screens. Their functions vary from screen to screen, but generally the right (circle) key provides affirmative options and the left (square) key provides negative options.

2.7.2 Arrow (navigation) keys

2.7.2.a The arrow (navigation) keys provide **Left**, **Right**, **Up** and **Down** control and allow the user to move to options available on the screen. The selected option becomes highlighted.

2.7.2.b The left and right arrow keys scroll through the main menu options.

2.7.3 Entering characters

2.7.3.a Character entry is similar to a mobile phone where numbered keys can be pressed sequentially to select the required character.

2.7.3.b The order of the characters is dependent on context. For example when used to enter:

Patient ID
Numbers are presented first then capitals, e.g. 2ABC.

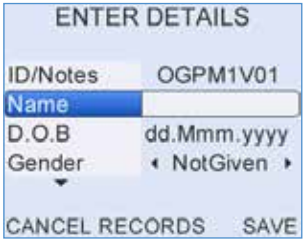
Family Name
For the first character capitals are presented first, then lower case then numbers, e.g. ABCabc2. For subsequent characters lower case is shown first, e.g. abcABC2.

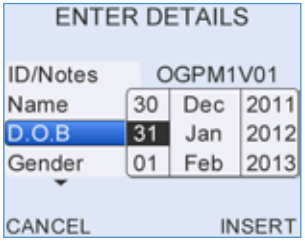
2.7.3.c More characters can be stored than can be displayed on the screen. Arrows are displayed to indicate that the string continues to the left or the right Pressing the appropriate **Arrow** navigation keys will display the hidden characters.

2.7.4 Foreign character table

2.7.4.a A foreign character pop-up table can be accessed by holding down the 1 key for 1.5 sec. Use the Arrow keys to navigate around the table. Select **Insert** to enter the required character or select **Cancel** to close the table window.

2.7.5 Entering dates





2.7.5.a A right arrow symbol is shown at the end of a date field.

2.7.5.b When the field is highlighted, press the right arrow key to access the calendar pop-up table. The day will be highlighted first and can be altered using the up and down arrow keys. Continue to use the left and right arrow keys to jump between the Day/Month/Year and the up and down arrow keys to select the required date.

2.7.5.c Select **Insert** to accept the date displayed or **Cancel** to ignore the changes.

2.7.5.d If the date has not been edited, it will remain as dd.Mmm.yyy by default.

2.7.5.e For Date of Birth entry (**D.O.B**) the Otoport will not permit entry of a future date. **Invalid D.O.B.** will be displayed briefly at the top of the screen then the date of birth will revert to today's date. Re-edit and confirm the D.O.B. if necessary.

2.7.6 Choice bars

2.7.6.a Left and right arrow keys are used to move through choice bar options. For example when entering patient details in the **Gender** field, pressing the right arrow key will rotate the selected option between **Not Given**, **Male**, **Female** and **Unknown**. Choice bars options are enclosed by arrow graphics.

2.7.7 Deleting characters

2.7.7.a The bottom right hand **Contrast/Delete** key is used as a delete key. If the cursor is at the end of a row of characters, press this key to delete the last character.

2.7.7.b Left and right arrow keys can be used to scroll back through the text. The selected blinking character can be replaced using the keypad data entry keys or deleted with the delete key. Continue to press the delete key to erase characters to the right of the cursor.

2.7.8 Backlight

2.7.8.a The screen and keypad are backlit to assist in testing in dimly lit environments. The backlight stays on for 7 seconds following any key press and remains on during testing. The backlight can be configured (see chapter 8 **Configuration**).

2.7.9 Stimulus and Noise OK indicators (blue LEDs)

2.7.9.a The two blue LEDs above the screen on the Otoport give an indication of whether stimulus and noise levels are acceptable for data collection.

2.7.9.b The Stimulus LED is marked with an S. It is lit when the stimulus level recorded by the probe microphone is within the expected range.

2.7.9.c The Noise OK LED is marked with an N. It is lit when the noise level recorded by the probe microphone is below the set noise reject level (see chapter 8 **Configuration**).

2.7.10 Hard reset

2.7.10.a In the unlikely event that the Otoport fails to respond to user control, hold the On/Off key down for 10 seconds, in order to reset the device. You may then switch on the device as normal.

2.8 Connecting the probe

2.8.a Prior to the testing session, connect the probe to the Otoport.

2.8.b The probe plug contains a ‘key’ that must be aligned with the ‘keyway’ in the probe socket on the Otoport.

Probe key

Socket keyway

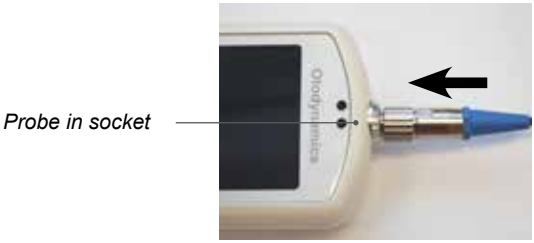
2.8.c The arrow at the front of the probe plug indicates the position of the ‘key’ and should be aligned with the front of the Otoport.

Arrow

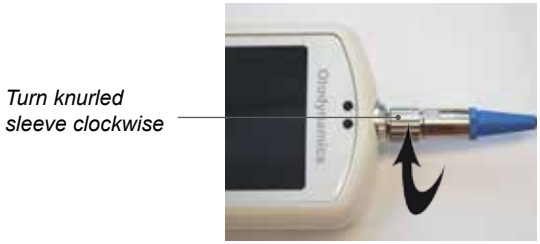
2.8.d It is possible to feel when the probe key is aligned as the probe will mate with the socket easily.

Align arrow with front of Otoport

2.8.e Push the probe into the socket until it hits the end stop. DO NOT force in the probe.



2.8.f Screw up the **knurled sleeve** in a clockwise direction until finger tight.



2.9 Disconnecting the probe

2.9.a To disconnect the probe, unscrew the **knurled sleeve** in an anticlockwise direction until the thread is disengaged.

2.9.b Then gently pull the probe out from the probe socket.

2.9.c

Important Note:

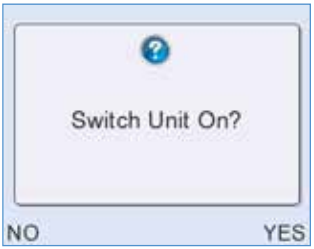
Do **NOT** attempt to screw or unscrew the probe by holding the main probe body (smooth chrome section).

This will result in damage to the probe and will invalidate the probe warranty.

3 Switching On

3.1 Switch on screen

3.1.a To switch on the Otoport press the green **On/Off power** key found at the bottom left of the keypad. The display screen will show **Switch Unit On?**.



3.1.b Select **Yes** to confirm Otoport switch on, or **No** to turn the unit off again. If **Yes** or **No** are not selected within two seconds of pressing the on/off power key, the device will automatically turn off. The unit will turn off if any key other than **Yes** is selected. This is to prevent accidental switch on during transit.

3.2 Logo screen

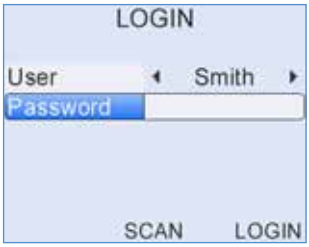
3.2.a Following switch on, an Otodynamics' logo animation is displayed whilst the device performs a series of hardware system checks. In the unlikely event of any of the systems checks failing, an error message will be displayed (see chapter 16.5 **Hardware fault messages** for details).

3.2.b A battery graphic will appear to the right of the logo to provide an indication of the **Battery Power** remaining. Please refer to chapter 15 **Otoport Power** for battery information.

3.2.c The date and time are also shown at the top of the screen and can be reset if necessary via the **Configuration** menu (see chapter 8).

3.2.d Selecting **Config** during start up takes the user to the **Configuration** menu where probe test, test settings, date, time, system details and users may be viewed or edited (see chapter 8 **Configuration**).

3.3 Login



3.3.a If **Login** is **on** (see chapter 8.6) the login screen will be displayed and the user will be required to enter a name and password.

3.3.b Use the left and right arrow keys to choose the correct user name from the choice bar.

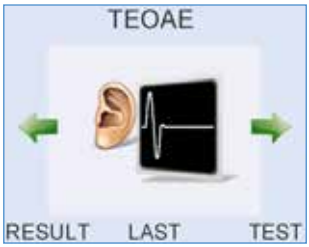
3.3.c After the user is selected, use the data entry keypad to enter a corresponding **Password**, if set for that user.

3.3.d To improve security during **Login**, a * symbol will replace each character as it is entered in the **Password** field. To review charcters that have been entered, simply scroll back through the * using the left and right arrow keys.

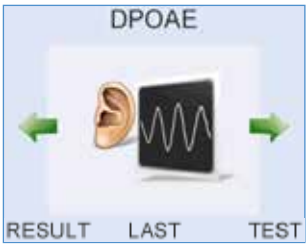
3.3.e When the **User** and **Password** have been chosen, select **Login** to access the device. If the **Password** has been entered incorrectly, then a warning message will appear as below:

3.4 Main menu

3.4.a You are then presented with the main menu screen. From here you can view the **Result** of the last test, select the **Last** patient tested or perform a **Test**. The heading on the screen indicates whether the Otoport is a TEOAE or DPOAE model.

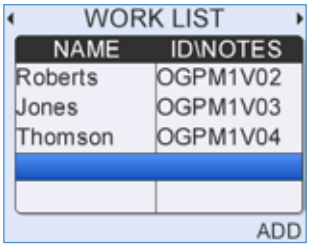


TEOAE model



DPOAE Model

3.4.b Use the left and right arrows to access **Records** and the **Work List**. See chapters 6 and 7 for further details.



4 Test preparation

4.1 General checks before testing

4.1.a Ensure the Otoport is charged (see chapter 15 **Otoport power** for information).

4.1.b Ensure the Otoport weekly checks are being regularly conducted (see chapter 11 **Probe checks** for information).

4.1.c Do not run an OAE test if there is any discharge from the ear to be tested.

4.1.d Choose a quiet room, without background noises.

4.1.e Ensure the patient is comfortable and settled.

4.1.f Ensure you can clearly see the ear to be tested.

4.2 Connecting the probe

4.2.a Prior to the testing session, connect the probe to the Otoport.

4.3 Tip selection and probe fitting

4.3.a Appropriate tip selection and good probe fit are essential to ensure successful OAE recordings. A good probe fit will help to block out external noise and enhance the OAE signal. The Otoport is supplied with a full range of tips to fit all ear canal sizes. When selecting a tip, first inspect the ear to be tested to assess its size and to check that it is clear and free from debris. If debris subsequently enters the probe sound tubes, do not attempt to clean them; the coupler tubes should be changed. The correct size tip will look slightly larger than the ear canal and should fit snugly, forming a complete seal with the ear canal wall.

4.3.1 Fitting for newborns

4.3.1.a Gently lift the pinna upwards, away from the baby's head, and then towards the back of the head. This will open the ear canal.

4.3.1.b Insert the probe at approximately 10 o'clock (for left ear) or 2 o'clock (for right ear).

4.3.1.c Turn the probe ear piece to 12 o'clock.

4.3.1.d Hold the probe for several seconds. Then release the pinna and let go of the probe.

4.3.2 Fitting for children and adults

4.3.2.a Line up the probe to 7 o'clock (for left ear) or 5 o'clock (for right ear).

4.3.2.b Push the probe firmly into the ear canal at this angle.

4.3.2.c Hold the probe for several seconds. Then release the probe.

4.3.2.d No discomfort should be felt by the patient. The weight of the probe cable should be supported to minimise the risk of the probe being pulled out during testing. Use the probe cable clip supplied, ensuring there is sufficient slack in the cable to allow for movement of the patient's head. If the correct tip is used, the probe should stay in place without aid. However, it is acceptable to hold the probe gently in the ear if the patient is restless.

4.4 Helpful hints

4.4.a The most frequent cause of unsuccessful OAE recordings is failure to fit the probe correctly, so that it is deep enough in the ear canal. The presence of fluid and debris in the ear canal or middle ear will also inhibit recordings.

4.4.b If a pass result is not obtained, remove the probe and inspect the probe tip. Discard the tip if it has collected debris or moisture. Also check that the probe coupler tubes are clear and replace these if a blockage is noticed. Then refit the probe and try again. Problems of debris and middle ear fluid occur mostly in babies younger than 6 hours and are often cleared by feeding or turning the baby. If there is no success during the first OAE testing attempts, a second OAE testing session usually brings success when the ear has had time to clear.

4.4.c Babies are best tested when they are sleeping or sleepy and successful OAE recordings are most often made one hour after a feed. The baby may settle down more easily if swaddled. Babies older than one month may be too active to test. When testing a child it can help to entertain them during the test, so they don't become too restless. Try to keep the probe cable out of their reach; using the probe cable clip may help. Instruct adults to be still and remain quiet.

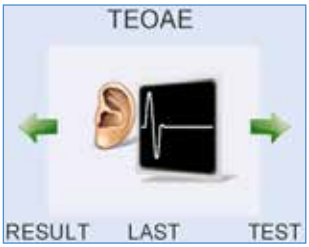
4.4.d Noises from the patient may not prevent successful recording, but will increase the test time. Constant environmental background noise, for example from air conditioning or machinery, may prevent a successful test. Testing should only be conducted in rooms where the noise level recording on the Otoport is mainly below the noise reject level when the probe is not fitted in the ear. Some intermittent noise can be tolerated, but constant high noise will inhibit successful recordings.

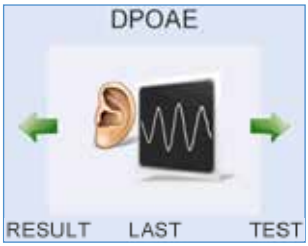
4.5 OAEs and screening

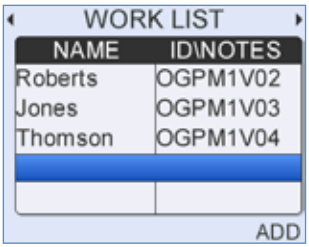
4.5.a OAE testing is commonly used as the primary hearing screen in newborns with no known hearing loss risk factors. Failure to show a strong OAE indicates that further testing or observation is necessary.

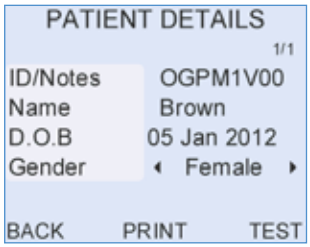
4.5.b OAE testing is frequently used as the initial screen within the 'at risk' population. Passing the OAE test indicates that normal middle ear and cochlear function is present. The specific risks must be evaluated to determine whether ABR (auditory brainstem response) testing is necessary, even after a pass at OAE. Certain clinical conditions indicate the possibility of retro-cochlear/neurological disorders which the OAE test cannot detect.

5 Test









5.0.a A **Test** may be started by selecting **Test** or **Last** from the main menu screen, from the **Worklist** or by selecting **Test** from the **Patient** details screen, in the **Records** area.

5.0.b You will not be able to start a test if the Otoport is connected to a PC or power supply.

5.1 Checkfit

5.1.1 Checkfit display

5.1.1.a It is important to perform a test in the appropriate conditions. The **Checkfit** screen allows a user to assess the testing environment. Conditions such as high ambient noise, poor fit of the probe in the ear (including leaks) and blocked probes can be detected before starting the test.

5.1.1.b Excessive noise or a poor probe fit may mean that the test cannot be performed or that the quality of data collected may be too low for an accurate test result to be determined.

5.1.1.c Fit Size Indicator

5.1.1.d The **Checkfit** screen shows a Fit Size Indicator; this shows a series of ears of increasing size, indicating increasing ear canal volumes. The size of ear canal detected in Checkfit is indicated by an arrow.

5.1.1.e During **Checkfit** the Otoport repeatedly plays a click at a fixed level and records the sound level this click produces in the ear.

5.1.1.f The sound level recorded depends on the fit of the probe and the size of the ear canal in which the probe is inserted.

5.1.1.g Ear canal size increases from birth to adulthood. So, given a good probe fit the sound level recorded correlates with the age of the patient.

5.1.1.h For example, if the arrow is below the smallest ear, this indicates that the sound level recorded is that which would be expected from a small ear canal. You would expect this if you were testing a baby.

5.1.1.i Individual ear canals vary considerably in size, so the indication of canal size can only be used as an approximate guide to probe fit.

5.1.1.j If the position of the **Fit Size Indicator** corresponds with the age of the patient and **Checkfit** is displayed on the top of the screen then the probe fit and the test conditions are adequate for testing. The Stimulus and Noise OK indicators (above the screen) should also be illuminated. Select **Start** to continue the test.

5.1.1.k If there is a disagreement between the **Fit Size Indicator** and the ear canal size expected of your patient, then there may be a problem with the probe or the probe fit. For example: an indication of a large ear canal in a neonate may occur if the probe has fallen out of the ear or if the probe is blocked; an indication of a small ear canal in an adult may occur because of wax blocking the canal.

5.1.1.l ## Noise Level Indicator

5.1.1.m A Noise Level Indicator is shown on the right of the **Checkfit** screen. The red/green bar moves in response to changes in noise. For good testing conditions the bar should be green and remain consistently below the Noise Reject Level, which is represented by the horizontal line across the Noise Level Indicator. In poor testing conditions, when the noise level is above the Noise Reject level, the bar will be red.

5.1.1.n The letter below the indicator represents the noise reject threshold level. This can be altered using the up and down arrow keys.

5.1.1.o Generally higher noise reject can give faster data collection but poorer quality data. The best noise reject setting depends on both test conditions and the strength of the emission being tested. Strong emissions may be detected in a noisy environment with a high noise reject threshold. Weak emissions may only be detected in a quiet environment with a low noise reject threshold.

5.1.1.p ## Checkfit condition information

5.3.1.q When conditions are good for data collection **TE TEST** (or **DP TEST**) will be shown at the top of the screen and progress indicators will move either side of the title to show that a test is currently running.

5.1.1.r **Check Probe Fit** is shown if the stimulus level falls outside the accepted range.

5.1.1.s **Noisy** appears if the noise level is consistently above the Noise Reject Level for a period of time.

5.1.1.t **Ringing** is displayed when there is obvious oscillation within the **Stimulus Waveform** after the initial expected positive and negative peaks.

5.1.1.u The following table describes what **Highlighted Message** will appear if more than one condition is met.

Consistent High Noise	Stimulus Out of Range	Stimulus Ringing	Highlighted Message
No	No	No	Checkfit
Yes	No	No	Noisy
No	Yes	No	Check Probe Fit
No	No	Yes	Ringing
Yes	Yes	No	Check Probe Fit
Yes	No	Yes	Ringing
No	Yes	Yes	Check Probe Fit
Yes	Yes	Yes	Check Probe Fit

5.2 TE test (TEOAE model)

5.2.a During testing the Otoport plays a series of clicks into the ear and records the response. The OAE signal is very small and difficult to distinguish from the noise made by other sounds in the room and by the patient. The longer the Otoport records for, the easier it is to distinguish the OAE signal from the noise. The Otoport looks at the ratio of the OAE signal to the noise; this is known as the Signal to Noise Ratio or SNR. The Otoport measures the SNR in a number of different frequency bands. The pass criteria is set in the **Configuration** area (see chapter 8 **Configuration**). The default pass criteria is an SNR of 6dB and a minimum signal of >-5dBSPL in at least two frequency bands.

5.2.b It is the responsibility of the user to ensure that the pass criteria set meet their requirements.

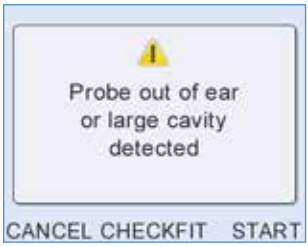
5.2.1 Stimulus adjustment

5.2.1.a When **START** is selected, the Otoport will attempt to adjust the stimulus level to the required level. The message **Adjusting…** is displayed while this is happening. Once the correct level has been reached, by default the Otoport automatically begins the test.

5.2.1.b The Otoport may not be able to adjust the stimulus to the correct level in noisy environments, if the probe fit is poor or if the patient's ear canal is unusually large. If the correct stimulus level is not reached after 10 seconds then the message **Stim out of range** will be displayed. The user then has the option to **Continue** or **Cancel** the test.

5.2.1.c In these circumstances Otodynamics recommends that the test is cancelled. Efforts should then be made to improve the probe fit, check the probe coupler tubes are clear and improve the test environment. If adjustment continues to fail, regardless of the position of the probe in the ear, it is likely that the probe has become blocked. In this case, inspect the probe coupler tubes and replace if necessary, then run probe checks (see chapter 11 **Probe Checks**) to test the probe and Otoport performance. If stimulus adjustment is still unsuccessful, continuing the test may provide useful results but it is likely that the stimulus level will be incorrect. This will affect the level of OAE recorded.

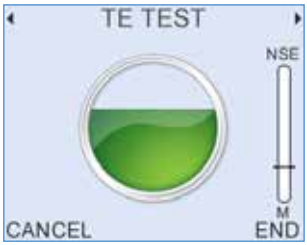
5.2.1.d With Neonate mode On, the user is warned if the response from the probe indicates a large ear canal (as shown below, see also section 8.3.5).



5.2.2 Test screens

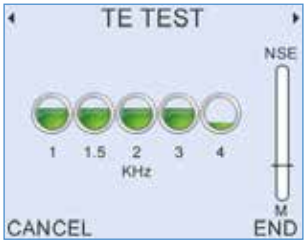
5.2.2.a The test screen display depends upon the display option set from the **Configuration** menu (see chapter 8 **Configuration**). The default display is a simple **One circle** view.

5.2.2.b One circle



5.2.2.c In the **One circle** display a single circle represents progress towards meeting the pass criteria. The level of green displayed within the circle represents the strength of the OAE detected compared with the level of noise recorded (the SNR). A fuller circle indicates that the SNR and signal level are closer to the pass criteria.

5.2.2.d Circles



5.2.2.e The **Circles** display shows a series of small circles like the large circle in the simple **One circle** display. Each small circle represents the SNR recorded in a particular ½ octave frequency band when the minimum signal level is met. If the minimum signal level is not met, the circle will not fill completely, even if SNR criterion has been achieved. The numbers below the circles indicate the kHz frequency of the centre of the ½ octave band.

5.2.2.f

Noise level indicator

5.2.2.g A Noise Level Indicator is shown on the right of the **Checkfit** screen. The bar moves in response to changes in noise. For good testing conditions the bar should be consistently below the Noise Reject Level, which is represented by the horizontal line across the Noise Level Indicator. The bar is filled red if the level is above the threshold and green if it is below. The noise level shown is calculated from the peak sound level recorded within each response window.

5.2.2.h The letter below the indicator represents the noise reject threshold level. This can be altered using the up and down arrow keys.

5.2.2.i The noise level indicator allows continuous monitoring of the noise level during a test.

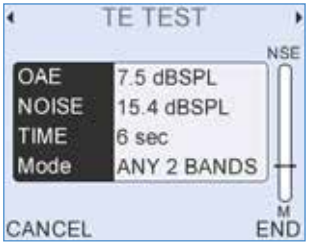
5.2.2.j

Test condition information

5.2.2.k When conditions are good for data collection **TE TEST** will be shown at the top of the screen and progress indicators will move either side of the title to show that a test is currently running. If test conditions are not optimum, a highlighted message will appear, indicating the problem. (See 5.1.1.p).

5.2.2.l

Data summary screen



5.2.2.m Pressing the left and right arrow keys displays the **Data Summary Screen**.

5.2.2.n This screen displays the current total OAE, the total noise, the time elapsed and the current test mode. Press the left and right arrow keys again to return to the test screen.

5.2.3 Test stop reasons

5.2.3.a There are four possible ways in which a test can stop: **AutoStop**, **Maximum NLo Sweeps**, **Test Timeout** and **Manual End**. When the test stops the data collected is assessed and a result given as a pop-up graphic and then written highlighted at the top of the test screen. The Otoport will beep once if a test has stopped with a **TEOAE Pass** result and will beep twice if the test has stopped with any other result.

5.2.3.b AutoStop

5.2.3.c If the test data collected meets the set pass criteria then the test will AutoStop and a large checkmark will be displayed.

5.2.3.d Maximum number of NLo sweeps

5.2.3.e If a test has not met the set pass criteria it will stop when the **Maximum NLo Sweeps** (NLo sweeps are recordings made with a noise level below the rejection threshold) is reached. This is a representation of the amount of good data sweeps required before a **No valid OAE** result can be given.

5.2.3.f Test timeout

5.2.3.g If a test has not met the set pass criteria and the noise is consistently above the **Noise Reject Threshold Level** so that the **Maximum NLo Sweeps** cannot be achieved, then the test will stop after 300 seconds, regardless of the amount of good data collected. This is to prevent overexposure of stimulus in an ear and to limit the test time to allow for reassessment of the ambient noise and of probe fit before a retest.

5.2.3.h Manual end

5.2.3.i Selecting **End** at any time will stop the test.

5.2.3.j

Pausing and cancelling the test

5.2.3.k

You may wish to pause a test for instance during periods of noise. When the test is paused, it is possible to cancel the test and discard the data. Select **Cancel** to pause the test. Select **Yes** to end the test and discard the data, **No** to resume the test and **Checkfit** to restart the test at the Checkfit stage.

5.2.4 Test results

5.2.4.a The following table lists all possible test results with the associated result graphic and gives an explanation of the circumstances under which each result would be shown.

Test Result	Description
TEOAE Pass	The data collected has met the criteria set. The optimum test setting will depend on your application (see 8.3 **Test settings**)
Note:	*The following results will only occur if a TEOAE Pass is not obtained*
Noisy	The noisy data collected is three times greater than the low noise data collected
Poor Probe Fit	Probe movement has been detected
No Valid OAE	The data collected has not met the set pass criteria and the test conditions were acceptable
Too Few Bands	Insufficient bands meet their pass criteria
Stopped Too Soon	The test was ended manually before the required minimum amount of data has been collected

5.3 DP Test (DPOAE model)

5.3.a During testing the Otoport plays pairs of tones at different frequencies into the ear and records the response. The OAE signal is very small and difficult to distinguish from the noise made by other sounds in the room and by the patient. The longer the Otoport records for, the easier it is to distinguish the OAE signal from the noise. The Otoport looks at the ratio of the OAE signal to the noise; this is known as the Signal to Noise Ratio or SNR. The Otoport measures the SNR in a number of different frequencies. The pass criteria is set in the **Configuration** area (see chapter 8 **Configuration**). The default pass criteria is an SNR of 6dB and a minimum signal of >-5dBSPL in at least three frequency bands.

5.3.b It is the responsibility of the user to ensure that the pass criteria set meet their requirements.

5.3.1 DP stimulus calibration

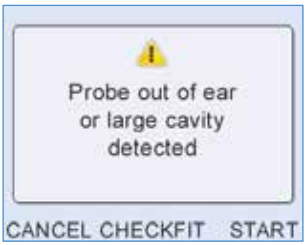
5.3.1.a Before starting the test the Otoport will calibrate the levels of the stimulus tones which are to be used in the test. This is necessary to account for the acoustic properties of individual patients' ear canals. If the required levels cannot be reached then the Otoport will display the message **Unable to calibrate. Check probe fit** and return to the checkfit screen.

5.3.1.b If calibration fails, check the probe fit and check that the probe coupler tubes are clear. Excessive noise may inhibit calibration, so ensure environmental noise levels are low. Make sure a DP (UGD - grey) probe is connected to the Otoport and not a TE (UGS - red) probe.

5.3.1.c If calibration continues to fail, regardless of the position of the probe in the ear, it is likely that the probe has become blocked. In this case, inspect the probe coupler tubes and replace if necessary, then run **Probe Checks** (see chapter 11) to test the probe and Otoport performance.

5.3.1.d Following **Stimulus Calibration**, the OAE recording begins and data is collected.

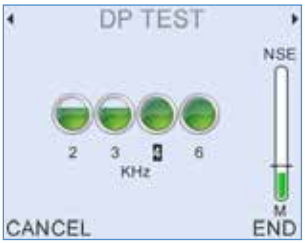
5.3.1.e With Neonate mode On, the user is warned if the response from the probe indicates a large ear canal (see 5.2.1.d graphic and section 8.3.5).



5.3.2 Test screen

5.3.2.a The Otoport looks at the ratio of the OAE signal to the noise; this is known as the Signal to Noise Ratio or SNR. The Otoport measures the SNR in a number of different frequencies.

5.3.2.b The display shows a series of small circles, each representing the SNR recorded at a particular DP frequency. The numbers below the circles indicate the F2 frequency in kHz.



5.3.2.c The pass criteria are set in the **Configuration** area (see chapter 8 **Configuration**). The default pass criteria are an SNR of 6dB, a minimum signal of >-5dBSPL and at least 1.28s of data collected in at least three frequency bands.

5.3.2.d It is the responsibility of the user to ensure that the pass criteria set meet their requirements.

5.3.2.e Noise level indicator

5.3.2.f A Noise Level Indicator is shown on the right of the **Checkfit** screen. The bar moves in response to changes in noise. For good testing conditions the bar should be consistently below the Noise Reject Level, which is represented by the horizontal line across the Noise Level Indicator. The bar is filled red if the level is above the threshold and green if it is below. The noise level shown is calculated from the peak sound level recorded within each response window.

5.3.2.g The letter below the indicator represents the noise reject threshold level. This can be altered using the up and down arrow keys.

5.3.2.h The noise level indicator allows continuous monitoring of the noise level during a test.

5.3.2.i Test condition information

5.3.2.j When conditions are good for data collection **DP TEST** will be shown at the top of the screen and progress indicators will move either side of the title to show that a test is currently running.

5.3.3 Test stop reasons

5.3.3.a There are three possible ways in which a test can stop: **AutoStop**, **Test Timeout** and **Manual End**. When the test stops the data collected is assessed and a result given as a pop-up graphic and then written highlighted at the top of the test screen. The Otoport will beep once if a test has stopped with a **DPOAE Pass** result and will beep twice if the test has stopped with any other result. AutoStop and Stopping (Pass) criteria are configured in the test settings area (section 8.3).

5.3.3.b AutoStop

5.3.3.c If the test data collected meets the set pass criteria then the test will AutoStop and a large checkmark will be displayed.

5.3.3.d Test timeout

5.3.3.e If a test has not met the set pass criteria then the test will stop after 60 seconds.

5.3.3.f

Manual end

5.3.3.g Selecting **End** at any time will stop the test.

5.3.3.h

Pausing and cancelling the test

5.3.3.i You may wish to pause a test for instance during periods of noise. When the test is paused, it is possible to cancel the test and discard the data. Select **Cancel** to pause the test. Select **Yes** to end the test and discard the data, **No** to resume the test and **Checkfit** to restart the test at the Checkfit stage.

5.3.4 Test results

5.3.4.a The following table lists all possible test results with the associated result graphic and gives an explanation of the circumstances under which each result would be shown.

Test Result	Description
DPOAE Pass	The data collected has met the criteria set. The optimum test setting will depend on your application, e.g. screening or clinical measurement (see 8.3 **Test settings**)
Note:	*The following results will only occur if a DPOAE Pass is not obtained*
Noisy	The noisy data collected is three times greater than the low noise data collected
Poor Probe Fit	Probe fit movement is detected that results in less than 85% of stimuli reaching calibration levels
No Valid OAE	The data collected has not met the set pass criteria and the test conditions were acceptable
Too Few Bands	Insufficient bands meet their pass criteria
Stopped Too Soon	The test has been ended manually before the required minimum amount of data has been collected

5.4 Quick Save option

5.4.a The options available from the test result screen depend on the **Quick Save** option (see chapter 8 **Configuration**)

5.4.1 Quick Save On

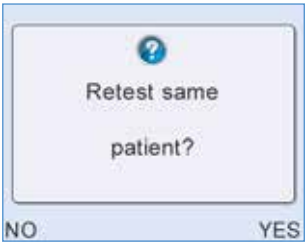
5.4.1.a If **Quick Save** is **On,** select **Left** to save the test to the left ear, or **Right** to save to the right ear.

5.4.1.b The test will be saved to the current patient or will be given an automatic ID and name. This name and ID may be edited by selecting **Last** from the main menu screen (see chapter 5.8).

5.4.1.c If **Automatic print** is selected (see chapter 8 **Configuration**), the print routine will be activated at this stage. After printing or immediately after saving, the unit will return to the **Main Menu**.

5.4.1.d Select **Cancel** to proceed without saving the test. The user will be prompted to confirm **Cancel without save**.

5.4.1.e After the save is confirmed, the option to retest the same patient will be displayed. Select **Yes** to run another test on the same patient or **No** to return to the main menu.



5.4.2 Quick Save Off

5.4.2.a If **Quick Save** is **Off,** select **Save** to enter **Patient Details** and then save the ear tested**.**

5.4.2.b Select **Review** to view the data of the completed test, prior to saving.

5.4.2.c Select **Cancel** to discard the test result. A prompt requiring confirmation will be shown before the result is discarded.

5.5 Review

5.5.a The review screen shows the result of the test.

5.5.b If the display is set to **One Circle** (TE model only), a large checkmark is displayed to indicate a pass.

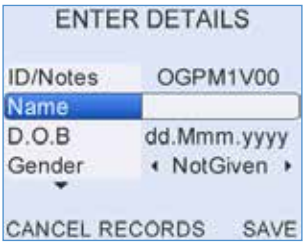
5.5.c If the display is set to **Circles**, full circles appear with a checkmark in each band that met pass criteria.

5.5.d Note:

If the SNR criteria are met but not the minimum signal criteria (see chapter 8 **Configuration**) a full circle will be displayed without a checkmark.

5.5.e The user may **Save** or **Cancel** the result from the **Review** screen (at the end of review).

5.6 # Save



5.6.a The **Enter details** screen is shown. The patient **ID** is filled with an automatically generated ID. The **Name** field displays **Auto**. The user may either save these details or overwrite them with alternative patient's details. If an ID is not required, this field may be used as a notes field.

5.6.b A Date of Birth (**D.O.B**) and **Gender** may also be added for the patient.

5.6.c A further three fields are available by scrolling down using the arrow keys. These are **NICU** (Yes or No), **Location** (Inpatient, Outpatient or At Home) and **Facility**.

5.6.d Note:

Only one **Facility** can be stored on the Otoport. It is not possible to store different facilities for different patients. If you wish to change the **Facility**, download and erase all test records from the Otoport first.

It is also not possible to set the **NICU** field to **Yes** if **Location** is set to **Outpatient** or **At home**. The fields are automatically corrected in this case.

5.6.e Alternatively, the user may select **Records** and choose an existing patient record to which the current results may be appended.

5.6.f If the test was run using the **Last** option test results will be saved with the same details as the last performed test.

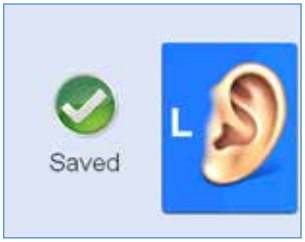
5.6.g If a scanner is installed on the Otoport, pressing any arrow key or key on the data entry panel will enable scan functions to enter patient details (see chapter 10 **Scanning** for more information).

5.6.h When the patient details are entered, select **Save** to store the result.

5.6.1 Select left or right ear

5.6.1.a The **Select Ear** screen represents the patient facing you. By defaulting to a **No Ear Choice** the **Select Ear** screen forces the user to choose an ear before the test can be saved. Press the right control key or the right arrow to select the **Left Ear** or press the left control key or the left arrow key to select the **Right Ear**.

5.6.1.b When the correct test ear has been selected press **Save** to save the test record to the database. A screen will be displayed briefly which confirms the test has been saved.



5.6.1.c The pop up message **Last Test Saved to Left/Right Ear. Save Test to Left/Right Ear Again?** may appear on **Save** if the patient's previous test was saved to the same ear. Select **Yes** to accept the current ear choice or **No** to return to the **Select Ear** screen.

5.6.1.d If **Auto print** is selected, the print routine will be activated at this stage.

5.7 Final review

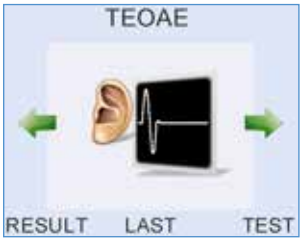
5.7.a After saving the user is given the opportunity for a final test review.

5.7.b There are options to **Print** the test results, to **Retest** the same patient or to **Finish** and return to the main menu.

5.7.c **Retest** will start a new test for the same patient. This can be used to retest the same ear or to test the opposite ear.

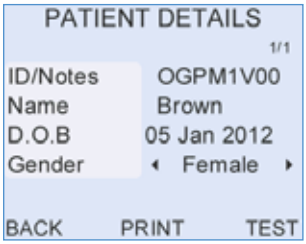
5.7.d **Print** will print the current test result or all the test results for the current patient (see chapter 9.2).

5.8 Last



5.8.a After one ear has been tested, further tests can be added to the same patient record by selecting **Last** from the main menu. Patient details can be amended and tests printed using this function.

5.8.b From the **Main Menu** select **Last**. The **Patient Details** screen is displayed.

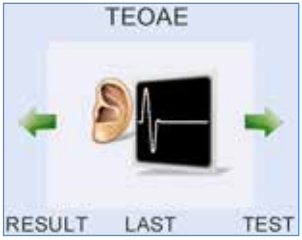


5.8.c Select **Test** to start a new test with the patient details displayed. Select **Print** to print all tests saved to this patient, or select **Back** to return to the main menu.

5.8.d The details stored can be edited by using the up/down keys to locate the correct field and then entering the new data using the keypad. All fields except **Location**, **Facility** and **NICU** can be edited. When an edit has been made the screen will change:

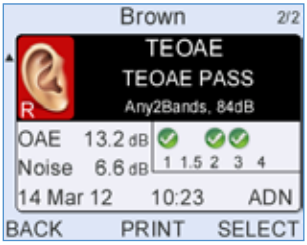
5.8.e If you are happy with the changes you have made select **Save**. To discard the changes select **Cancel**. Once changes are saved or cancelled the initial menu options return (**Back**, **Print** or **Test**).

5.9 Result



5.9.a Select Result to review the tests results for the current patient.

5.9.b **Select** displays the detailed result for this test. Select **Print** to print this test result.

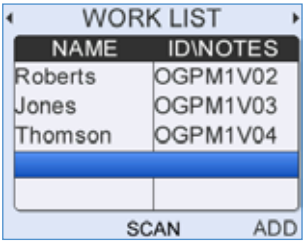


6 Worklist

6.0.a The Worklist allows details for multiple patients to be entered into the Otoport prior to testing. This eliminates the need for data entry while with the patient, allowing for faster, more flexible testing. The Worklist is **On** by default but can be switched **Off** in the Config area (see chapter 8).

6.0.b Access the Worklist by using the left or right navigation keys from the main menu.

6.1 Adding Patients



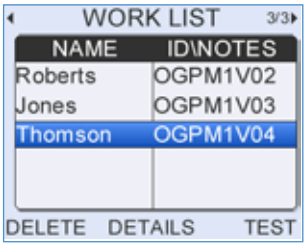
6.1.a If the worklist already contains patients, scroll down to the last line, which will be empty, then select **Add**. If your Otoport has RFID or Bluetooth facilities, you may enter patient details by selecting **Scan**.

6.1.b Complete the required details. The **ID/Notes** and **Name** fields are prefilled but can be over-written.

6.1.c When details are complete, select **Save** to save the details to the Worklist, **Test** to run a test on this patient, or **Back** to discard these patient details.

6.1.d Up to 50 patients may be added to the Worklist.

6.2 Testing from the worklist



6.2.a Scroll to the required patient. Select **Test** to begin testing this patient. When a test has been saved to a patient those details are removed from the Worklist.

6.3 Editing details

6.3.a Scroll to the required patient. Select **Details** to edit. The options available are the same as when adding a patient.

6.4 Deleting patients

6.4.a Scroll to the required patient. Select **Delete** to remove.

6.4.b Select **Yes** to delete the selected patient from the worklist. Select **All** to delete all of the patients from the worklist. Select **No** to return to the Worklist without deleting any patient details.

7 Records

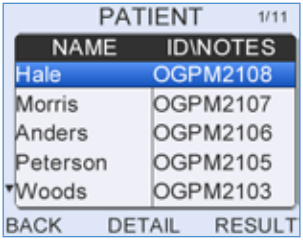
7.0.a The **Records** section allows the user to see the **Results** of previous tests and to view the **Details** of patients previously tested.

7.0.b Records may be via from the **Memory Status** screen accessed from the **Configuration** area (see chapter 8).

7.0.c **Records** also allows the user to select a previously tested patient for a new **test**.

7.0.d Selecting **Records** from the **Main Menu** takes the user to the **Patient List** screen.

7.1 Patient list



7.1.a The **Patient** list displays the **ID/Notes** field and **Name** of each patient. The up and Down arrow indicators to the left of the **Patient List** show that there are other **Patient Records** not currently visible on screen. At the top of the screen, the total number of patients in the list and the position of the current patient in the list are displayed: 12/34 indicates that the current patient is twelfth in a list of 34 patients.

7.1.b Use the up and down arrow keys to scroll through the list one **Patient Record** at a time. A selected patient will be shown as highlighted in the list.

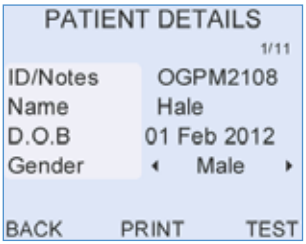
7.1.c Use the left and right arrow keys to skip through the **Patient List** ± 5 records at a time.

7.1.d Select **Detail** to review the complete **Patient Details** of the highlighted patient or to run a new **test** on this patient.

7.1.e Select **Result** when a patient is highlighted to inspect the patient's saved **Test Results**. A summary of each test will be shown.

7.1.f Select **Back** at any time to exit the **Patient List** screen and return to the main menu.

7.1.1 Details



7.1.1.a The **Patient Details** screen allows the user to see the **ID/Notes** field, **Name**, Date of Birth (**DOB**) and **Gender** stored for a particular patient.

7.1.1.b Selecting **Test** from this screen starts a new test, the result of which will be saved with the records of the selected patient.

7.1.1.c Selecting the up and down arrow keys on the patient details screen displays the patients before or after the current patient in the patient list. Selecting the left and right arrow screens displays the test results for the selected patient.

7.1.1.d Select **Back** to return to the **Patient** list.

7.1.2 Results

7.1.2.a The test summary gives an overview of the test result including ½ octave band passes and total OAE signal level. The diagrams following illustrate the features of a test summary screen.

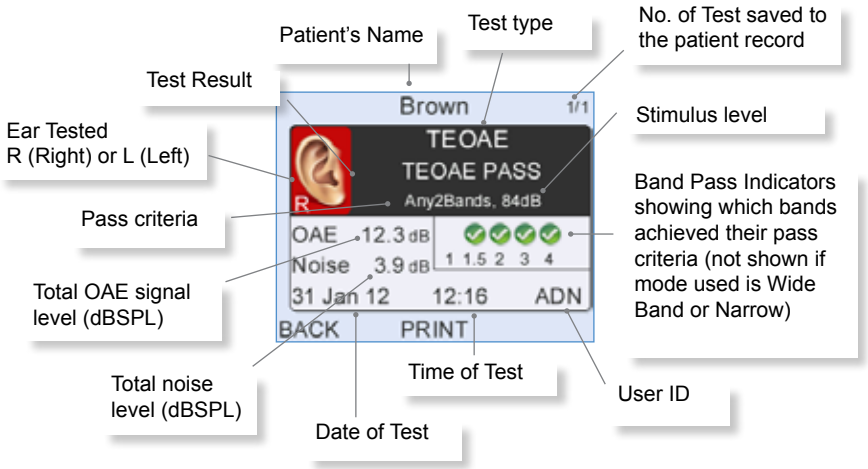
7.1.2.b The number of tests currently saved to the patient is displayed in the top right of the screen.

7.1.2.c The up and down arrow indicators to the left of the screen show that there are other saved test records for this patient. The left and right arrow indicators display the **Patient Details** for this patient.

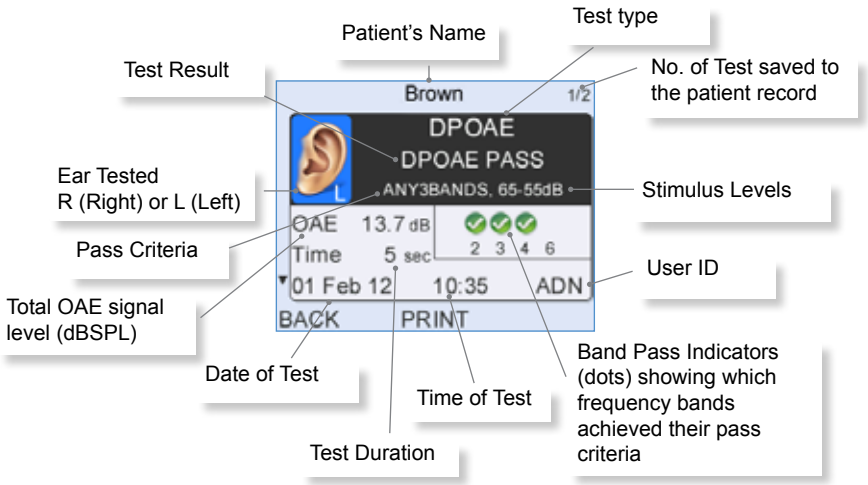
7.1.2.d Select **Print** to print an individual test record.

7.1.2.e Select **Back** at any time to exit the test summary screen and return to the **Patient List** to review tests of an alternative patient.

TEOAE test summary screen



DPOAE test summary screen



8 Configuration

8.1 Configuration menu

8.1.a The **Configuration** menu can be accessed by selecting **Config** on the logo screen after switching on.

8.1.b Select **Probe Test** to check the calibration performance of a probe.

8.1.c Select **Test Settings** to change test display and pass criteria.

8.1.d Select **Date & Time** to set the current date and time.

8.1.e Select **System** for memory, battery and system information.

8.1.f Select **Users** for login options.

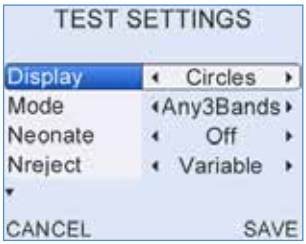
8.1.g Note:

Users without Admin rights will only have access to **Probe Test**. The other items will be hidden.

8.2 Probe test

8.2.a Details of how to perform a probe test are in chapter 11 **Probe checks**.

8.3 Test settings

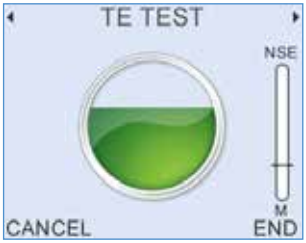


8.3.a Use the arrow keys to navigate and choose between the setup options (described below).

8.3.b Select **Save** to apply the settings changes you have made and return to the **Configuration** screen.

8.3.c Select **Cancel** to discard changes made to date and time settings and return to the **Configuration** screen.

8.3.1 Display (TEOAE)



8.3.1.a If **One circle** is selected, a single circle display is shown.

8.3.1.b An empty circle means that OAE data has not yet been recorded. The circle fills from the bottom, indicating good quality OAE data is being collected.

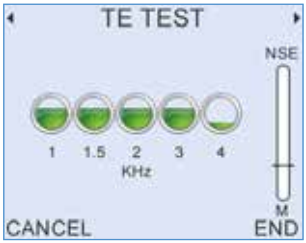
8.3.1.c As the circle fills, this indicates progress towards pass criteria.

8.3.1.d If all test criteria have been met, when the test is finished the circle will be completely filled and show a large checkmark.

8.3.1.e At the end of the test, a full circle may be displayed without a checkmark, indicating the SNR criteria have been met but not the minimum signal level criteria.

8.3.1.f The default setting is **One circle**.

8.3.1.g If **Circles** is selected the information on OAE levels in half octave frequency bands centred at 1, 1.5, 2, 3 and 4 kHz is displayed during testing.



8.3.1.h An empty circle means that OAE data has not yet been recorded at that frequency. The circle fills from the bottom, indicating good quality OAE data is being collected in that frequency region.

8.3.1.i As a circle fills, this indicates progress towards band pass criteria.

8.3.1.j If band pass criteria have been met, when the test has finished the circle representing that frequency band will be completely filled and show a large checkmark.

8.3.1.k When the test has finished, bands displaying a full circle without a checkmark have met the SNR criteria but not the minimum signal level criteria.

8.3.1.l The **Circles** setting is not available if **Mode** is set to **Wide Band** or **Narrow**.

8.3.2 Display (DPOAE)

8.3.2.a The display for the Otoport DP is **Circles** and cannot be changed. Each circle represents the SNR recorded at a particular frequency, as with the TEOAE **Circles** test display described above.

8.3.2.b Test frequencies (F2) for DPOAE are 2, 3, 4 and 6 kHz.

8.3.3 Mode (TEOAE)

8.3.3.a **Mode** sets the pass criteria for screening.

8.3.3.b The **Wide Band** setting requires a signal to noise ratio (SNR) of 6dB over the 841-4757Hz frequency range in order to meet the pass criteria.

8.3.3.c The **Narrow** setting also requires a signal to noise ratio (SNR) of 6dB over the 841-4757Hz frequency range in order to meet the pass criteria. However this setting uses a filter of 1.6-3.2kHz and a stimulus response window 4-10ms to reduce the impact of environmental noise on the recording. This makes this setting particularly appropriate for screening in a noisy environment.

8.3.3.d The **Any 2 Bands**, **Any 3 Bands** and **Any 4 Bands** settings require a 6dB SNR and a minimum signal level of -5dBSPL in each of the stated number of half octave frequency bands to meet the pass criteria.

8.3.3.e All test modes require a minimum overall (wide band) signal level of 0dBSPL and that the amount of data collected has reached a minimum level to met the pass criteria.

8.3.3.f The fixed and configurable test parameters are summarised in the tables below:

Fixed test parameters

Min sweeps (NLo)	30
Min total (wide band) OAE signal	0dBSPL
Min band signal	-5dBSPL
Stimulus level	84 +/- 1dB pe
Max test time	300 seconds
Max low noise (NLo) sweeps averaged	260 sweeps of 16 stimulus presentations
Ring reject	-20dB
Max ratio of stimulus peak to the level 3ms after stimulus presentation. Stimulus ring can hamper accurate OAE measurement	
Input filter	1189Hz - 4757Hz or 1600-3200Hz (narrow mode only)
The attenuation at these frequencies is 3dB. Attenuation increases by 80dB/decade below and 40dB/decade above these frequencies	

8.3.3.g The default setting is **Any 2 Bands**. However, it is recommended that you carefully choose pass criteria which suit your particular screening program.

Configurable test parameters

Name	Any 2	Any 3	Any 4	Wide	Narrow
Min pass bands	2	3	4	None	None
Min total (wide band) SNR	None	None	None	6dB	6dB
Min SNR per pass band	6dB	6dB	6dB	None	None
Filter (Hz)	1189-4757	1189-4757	1189-4757	1189-4757	1600-3200
Response Window (ms)	2-5-12.5	2-5-12.5	2-5-12.5	2-5-12.5	4-10

8.3.4 Mode (DPOAE)

8.3.4.a **Mode** sets the pass criteria for screening.

8.3.4.b The **Any 2 Bands**, **Any 3 Bands** and **Any 4 Bands** settings require a 6dB SNR and a minimum signal level of -5dBSPL in each of the stated number of half octave frequency bands to meet the pass criteria.

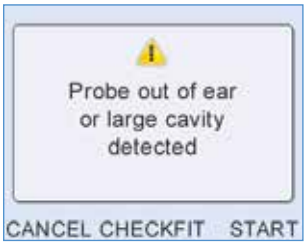
8.3.4.c The default setting is **Any 3 Bands**. However, it is recommended that pass criteria is carefully chosen to suit the particular OAE testing programme.

Fixed test parameters

Min band signal	-5dBSPL
Max test time	Approx 40s
Min data collected	0.64s per frequency

8.3.5 Neonate

8.3.5.a With **Neonate** setting **On** the user is warned if the response from the probe indicates a large ear canal. This provides an additional check of probe fit for users who are testing only babies.



8.3.5.b The warning message is displayed after checkfit and before test start. **Start** starts the test as normal. **Checkfit** returns the user to Checkfit. **Cancel** returns the user to the Main Menu.

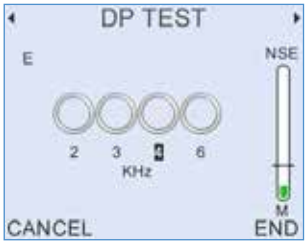
8.3.5.c Ear canal cavities greater than around 0.5cc will trigger the warning.

8.3.5.d With **Neonate** setting **Off**, no warning message is displayed if a large ear volume is detected.

8.3.6 NReject

8.3.6.a The threshold above which data is rejected can be fixed at **High**, **Medium** or **Low**. Alternatively, Variable can be selected allowing the reject level to be adjusted during checkfit and test.

8.3.7 Extend



8.3.7.a If **Extend** is **On**, the user has the option to extend the test beyond the normal maximum duration. This may be useful if the test result is very close to meeting the pass criteria at the normal test end. If **Extend** is **On**, the central key on the Otoport will show **Extend** when there are around 15 seconds of test time remaining. If the central soft key is pressed, an **E** will be displayed and the test will run until autostop criteria are met, it is manually stopped or the absolute limit for testing is reached.

8.3.8 Start

8.3.8.a With **Start** set to **On** (default), the testing will proceed from **Checkfit** to **Test** as soon as the Otoport detects a stable probe fit, without the need for the user to select **Start**.

8.3.8.b With **Start** set to **Off**, the user must initiate the test by selecting Start when the probe fit and test conditions are satisfactory.

8.3.8.c Irrespective of the **Start** setting, the **Start** key is available in order that the user can initiate a test.

8.3.9 DP Stims (DP only)

8.3.9.a This sets the target stimulus levels for the tones L1 and L2 that are represented during the test. The options available are:

60-50
60-55
65-50
65-55
70-70

8.3.9.b Higher intensities give a less sensitive hearing screen but may be necessary to record a response in older patients.

8.3.10 Noise mode

8.3.10.a **Noise mode** sets the method by which the noise floor in DP tests is calculated.

8.3.10.b The **Standard** mode implements a noise floor which is appropriate for **clinical** measurements in which high accuracy (in terms of the dBSPL of the OAE) is required at each frequency. A good Signal to Noise Ratio (SNR) in this mode indicates that a high accuracy of measurement has been reached.

8.3.10.c The **Rapid** mode is appropriate for secure detection of the presence of OAEs at a set number of frequencies for **screening** purposes. A good Signal to Noise Ratio (SNR) in this mode indicates high confidence level that an OAE is present.

8.3.10.d The Standard mode can also be used for screening but only in quiet test conditions. Tests will take longer than the Rapid mode and the confidence level of the result will exceed that needed for screening.

8.3.10.e Otodynamics does not recommend the Rapid mode for clinical measurements as the dBSPL accuracy may not be sufficient to quantify changes over time.

8.3.10.f Further details of the Noise Modes are included in chapter 19, **Mode of operation**.

8.4 Date and time

8.4.a The date and time set on the device can be altered in the **Date & Time** screen.

8.4.b When the **Date** field is highlighted press the right arrow key to access the calendar pop-up table. By default, the day will be highlighted first and can be altered using the up/ and down arrow keys. Continue to use the left and right arrow keys to jump between the Day/Month/Year and the up, and down arrow keys to select the required date.

8.4.c The date **Format** can be changed between dd.Mmm.yyyy and mm.dd.yyyy or dd.mm.yyyy via the choice bar.

8.4.d Select **Save** to set the current date and time settings and return to the **Configuration** screen.

8.4.e Select **Cancel** to discard changes made to date and time settings and return to the **Configuration** screen.

8.4.f

Important Note:

Do not set the date on the Otoport to an earlier date, if there is data stored on the device.

8.5 System

8.5.a The **System** screen allows users to view information on **Memory Status**, **Controls**, **Battery** power, **System Information** or to change the **Setup**.

8.5.1 Memory status

8.5.1.a The Otoport has the capacity to store up to 500 test records. The memory status screen displays the number of records currently stored and the percentage memory still available.

8.5.1.b Selecting **Erase** deletes all test records from the Otoport after requesting confirmation from the user. A screen confirming the **Erase** is then displayed and the user is returned to the main menu.

8.5.1.c If there is less than 10% free memory then the **Memory Status** screen will be displayed at start up.

8.5.1.d If there is 0% free memory then the **Memory Status** screen will be displayed automatically and no further tests may be performed until tests have been erased.

8.5.1.e The **Memory Status** screen will be displayed immediately after the 450th result has been saved warning the user that there is limited storage capacity left.

8.5.1.f If the **Memory Status** screen has been displayed because the Otoport memory is full or nearly full, the user will also have the option to **Download** data to a PC using Otolink.

8.5.2 Controls

8.5.2.a Volume

8.5.2.b Use the left and right arrow keys to decrease or increase the **Volume** level. To turn the sound off press the left arrow key repeatedly until **Sound Off** appears in the centre of the display.

8.5.2.c Select **Save** to accept the new **Volume** level.

8.5.2.d Select **Back** to ignore changes and return to the **Controls** Menu.

8.5.2.e Brightness

8.5.2.f The screen **Brightness** can be altered by pressing the left/right arrow keys.

8.5.2.g Select **Save** to accept the adjusted **Brightness** level.

8.5.2.h Select **Cancel** to ignore changes and return to the **Controls** Menu.

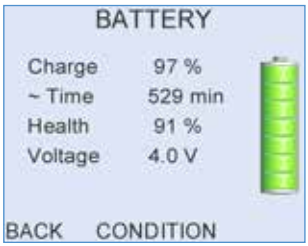
8.5.2.i Backlight

8.5.2.j Use the left and right arrow keys to toggle between the **Backlight** control choices for the screen and keypad. The backlight can be configured to be either always on or off, or on for a limited period of time (7, 10, 20 or 30 seconds) after a key press. Reduction in the backlight time will help to preserve battery charge during operation.

8.5.2.k Select **Save** to accept the **Backlight** setting.

8.5.2.l Select **Back** to ignore changes and return to the **Controls** Menu.

8.5.3 Battery



8.5.3.a The **Battery** screen provides information on the current battery status. The total **Battery Power** remaining is displayed as a percentage and as an approximate operation time. The calculated time is only an approximate indication as the power requirements will vary depending on the mode of operation.

8.5.3.b The **Battery** graphic on the right of the screen conveys the total remaining **Battery Power**. The battery segments are shaded according to the following criteria:

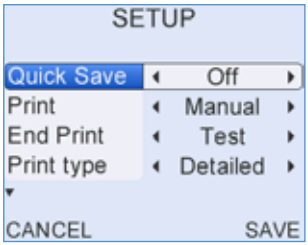
Segments Displayed	Battery Power (%)
7	95 - 100
6	75 - 94
5	55 - 74
4	40 - 54
3	30 - 39
2	20 - 29
1	10 - 19
0	< 10

8.5.3.c The **Battery Voltage** and **Health** values are provided as a diagnostic tool at the bottom of the screen.

8.5.3.d The battery graphic is also displayed on the **Logo** screen to inform the user of the **Battery Power** every time the device is switched on.

8.5.3.e Select **condition** to discharge the Otoport battery. See chapter 15 **Otoport power** for more information.

8.5.4 Setup



8.5.4.a Quick Save

8.5.4.b If **Quick Save** is **On** then test results can be saved from the test result screen with a single key push (see chapter 5 **Test** for details).

8.5.4.c If **Quick Save** is **Off** then options to enter patient details and review the test result are available before test is saved.

8.5.4.d Print

8.5.4.e If **Print** is set to **Automatic** then the test result is automatically printed after the test is saved.

8.5.4.f If **Print** is set to **Manual** then the user has the option to print the test after save.

8.5.4.g End Print

8.5.4.h If **End Print** is set to **Patient**, then all the test results for the current patient are printed at the end of the test.

8.5.4.i If **End Print** is set to **Test**, then only the last test performed is printed at the end of the test.

8.5.4.j Select **Save** to accept the setting and **Cancel** to discard any change.

8.5.4.k Note:

To avoid printout duplication, it is not possible to set **Print** to **Automatic** and **End Print** to **Patient**.

8.5.4.l

Print type

8.5.4.m Print type controls the length and detail contained in the Otoport printout. The **Summary** format prints only core patient and test details. The **Detailed** format prints a fuller set of patient and test quality details. (See chapter 9.2.4 for printout examples).

8.5.4.n

On connect

8.5.4.o **On connect** printing allows printing to be initiated as soon as a wired printer is connected. This is particularly useful if the Otoport is used with a Docking Station as it allows results to be printed as soon as the Otoport is dropped into the docking station.

8.5.4.p **On connect** may be turned **Off** or set to print the last **Test**, all unprinted tests for the last **Patient**, or **All** unprinted tests.

8.5.4.q Printing will only start if the Otoport is on and displaying one of the main module screens (see chapter 3.4).

8.5.4.r If **Cancel** is selected during the print, three options are available:

8.5.4.s If **Cancel Print** is selected, the Otoport will not attempt to automatically print the test(s) again (test may still be selected to be printed manually).

8.5.4.t If **Retry** is selected then printing will recommence.

8.5.4.u If **Stop On Connect** is selected then the **On connect** setting is turned off and the Otoport will not attempt to print tests on connection in future.

8.5.4.v

Worklist

8.5.4.w The **Worklist** allows details for multiple patients to be entered into the Otoport prior to testing. If **Worklist** is set to **On**, the list is accessible from the main menu (see chapter 6). If the **Worklist** is set to **Off**, it is not available.

8.5.4.x

Language

8.5.4.y Select the language you require using the left and right arrowkeys.

8.5.5 System info

8.5.5.a The **System Info** screen provides information on the Otoport.

8.5.5.b System Details

8.5.5.c **System Details** displays information for Otodynamics engineers. (See chapter 16.3 for further details).

8.5.5.d About

8.5.5.e The **About** screen provides information relating to the Otoport's identification and mode of operation. The firmware revision number and issue date is stated, together with the unit's unique hardware ID. If a probe is connected, the **Probe ID** will also be displayed for reference.

8.6 Users

8.6.a Select **Add New User** to enter details of a new user and save to the **User List**. Adding users to the Otoport allows test results to be attributed to individuals and allows password control of areas such as test setup.

8.6.b Select **View Users** to review, edit or delete users from the current **User List**.

8.6.c Select **Settings** to turn **Login** on or off.

8.6.d Select **Back** to return to the **Configuration Menu** screen.

8.6.1 Add New User

8.6.1.a To add a **New User**, complete the field entries shown on the **New User** screen. The following table describes the field choices available:

8.6.1.b

Field	Description	Max No. Characters
Name	User's name that appears at Login	8
User ID	The user's unique identification This is attached to a test record when saved to the database	3 (capitalised only)
Password	An alphanumeric password required for secure login (optional)	8 (capitalised only)
Admin	Select **Yes** to give the new user administrator rights. Select **No** to restrict the user to screener rights	N/A N/A

8.6.1.c The **User ID** is added to a saved test record to identify the user who performed the test. The **User ID** must therefore be unique and the message **Cannot Save! User ID already exists** will appear on **Save** if the chosen **User ID** is already associated with a current user. The device will return to the **New User** screen where the **User ID** field will be selected for editing.

8.6.1.d Selecting **Save** will add the user to the **User List**. The **User List** will appear with the newly saved user highlighted on screen. The message **Cannot Save! Please enter Name and User ID** may appear after selecting **Save** if either of the two fields have been left unfilled.

8.6.1.e Select **Cancel** to cancel the addition of a **New User** and return to the **Users** menu screen.

8.6.1.f A new user is given a choice of two levels of access rights. If **Yes** is selected in the administrator field, then the user will have full access to all the **Config** areas of the device. Select **No** to restrict the user's rights to only the **Probe** test area in **Config,** disabling access to higher level functions.

8.6.2 View Users

8.6.2.a The **User List** displays the **Name**, **Password** and **Status** of all users currently saved to the device.

8.6.2.b Select **Back** to exit the **User List** and return to the **Users Menu**.

8.6.2.c If a user has been assigned Administrator rights, an **A** will be present in the right hand Status column of the table.

8.6.2.d Edit user

8.6.2.e Select **Edit** to alter the details of a highlighted user.

8.6.2.f Select **Save** to save changes to the user's details and return to the **User List**.

8.6.2.g Select **Delete** to remove the selected user from the **User List**. A confirmation message will appear at the top of the screen. Select **Yes** to confirm the deletion or **No** to retain the user and return to the **Edit User** screen. It is not possible to delete the default "Admin" user.

8.6.2.h The message **Cannot Delete! User has tests in database** will appear if the user has performed tests that are still present within the database. It is necessary to delete all **Patient Records** from the device prior to deletion of users. Note: **Patient Results** should be downloaded to PC first.

8.6.2.i Select **Cancel** at any time to discard changes and return to the **User List**.

8.6.2.j Settings

8.6.2.k Select **Settings** to turn the **Login** facility **On** or **Off**.

8.6.2.l Select **Save** to save a change to the settings or **Cancel** to turn to the **Users** menu.

9 Printing

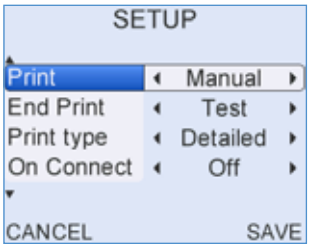
9.1 Printer accessory

9.1.a An Otoport mini printer is available as an optional accessory. The printer is used to create a paper record of the OAE test results recorded on the Otoport. The Otoport either communicates with the printer using Bluetooth wireless technology (optional) or with a custom printer cable.

9.2 When you can print

9.2.a The Otoport provides flexible options to print from various areas of the user interface, including printing at the end of the test.

9.2.b Print settings are located under **Configuration** in **System**, **Setup**.



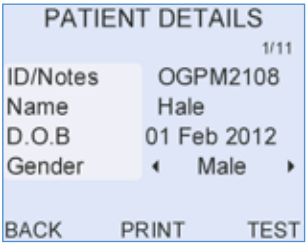
9.2.1 Printing at the end of a test

9.2.1.a When the OAE recording is finished and the result has been saved, select **Print** for a printout of the patient details and test results (see chapter 8.5.4.g).

9.2.2 Automatic print on save

9.2.2.a For efficiency, you can configure the Otoport to automatically print when the test is saved (see 8.5.4 **Setup** for details). The test is saved and a print initiated with one key push, rather than starting the printout separately.

9.2.3 Printing from records



9.2.3.a Results can be printed from the Otoport **Records** area. Select the patient for which you would like to print results (see the **Records** section for details of how to retrieve specific records from the database).

9.2.3.b To print patient details and all test results for that patient, select **Print** on the **Patient Details** screen.

9.2.3.c To print patient details and the result of a specific test, select the **Results** summary screen, scroll through the different tests for the patient (using the up and down arrow keys) and select **Print**.

9.2.4 Sample prints

OAE Test result

Otodynamics-Otoport
V3.15.0.0 GSN:MJ4

PATIENT DETAILS

ID/Notes: PASS
Name: JANE
D.O.B: 11.Nov.2009
Gender: Female
Comments:

Left Ear
TEOAE PASS

TEOAE: 9.8 dBSPL
Noise: -3.0 dBSPL

Technical details:

Stimulus :84 dB Pe
Protocol :Wide Band
N.Reject :Med Noisy :0%
Size(1-9):7 StimOK:97%
Stability:100% Repro :95%
Duration :3s User :ADN
Probe :GEN

Date: 11.Nov.2009 Time: 11:14

Detailed print

OAE Test result

ID/Notes: PASS
Name: JANE
D.O.B: 11.Nov.2009

Left Ear
TEOAE PASS

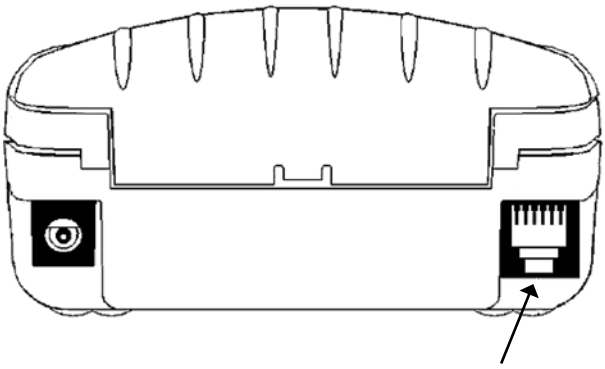
TEOAE: 9.8 dBSPL
Noise: -3.0 dBSPL

Date: 11.Nov.2009 Time: 11:14

Summary print

9.3 The printing process

9.3.a If you are using the wired printing method ensure the printer is connected to the Otoport using the printing cable provided. Connect the flat connector to the Otoport with the arrows facing upwards and the square connector to the back of the printer.



Printer cable socket

9.3.b The wireless printing method has a range of up to 10m in direct line of sight. It is recommended that the printing distance is reduced to 5m to help ensure robust communication. Remain within this range for the duration of the printout. Printouts will not complete if wireless communication is lost.

9.3.c The **Print** option will be shown in green if the Otoport is currently connected to a printer wirelessly. Otherwise, the **Print** option is shown in black.

9.3.d Note:

When using multiple Otoports with wireless connection to a single printer, the last Otoport to print must be switched off before another Otoport can print.

9.3.e The printer is powered from batteries, or can be connected to mains power when printing. Prior to printing, switch on the printer, using the power button on the top. When the printer is powered, a green light will be displayed. To save power, the printer will automatically switch off after 30 minutes of inactivity. If it is connected to mains power, the printer will remain on indefinitely.

9.3.f When a print is initiated, the Otoport will establish communication with the printer. The screen **Searching for Printer** will be displayed.

9.3.g The printout will then commence. Once the printout is completed the screen from which the print was initiated will be displayed.

9.3.h If there is a problem connecting to the printer using the wired method, the message **Printer not connected!** will be shown briefly and then the screen from which the print was initiated will be displayed. Check the printer is connected correctly and switched on then re-try.

9.3.i If there is a problem connecting to the printer using the wireless method, the following screen will be displayed providing options to cancel, search for an alternative printer (ALTER) or retry.

9.3.j To retry the print, ensure the printer is switched on and is within range (5m). Then select **Retry**. If printing wirelessly and you have an alternative printer available, select **Alter**. and the Otoport will connect to this printer.

9.3.k To cancel the printout, select **Cancel**.

9.3.l Once your print has completed, pull the paper sharply towards you across the serrated tear bar to remove the printout and store it with your patient records.

9.4 Printer fault detection

9.4.a The printer can detect if the paper roll has run out, or if the lid is open.

9.4.b Under these circumstances the Otoport will report the printer is out of paper and the following message will be displayed.

9.4.c Select **OK** to cancel the print job. Retry the printout when you have rectified the problem

9.4.d For wireless printing, print jobs sent to the printer will be stored (spooled) and printed when the detected condition is rectified. The printer's green light will flash when a print job is being stored.

9.5 Printer light summary

9.5.a The light at the front of the printer has a number of colour combinations, which indicate various conditions.

9.5.b **Constant green** - Normal operation, running on battery power.

9.5.c **Flashing green**- The printer is storing print information (spooling) that cannot be printed at the time (e.g no paper, or printer lid open)

9.5.d **Flashing green/orange** - Battery is being charged

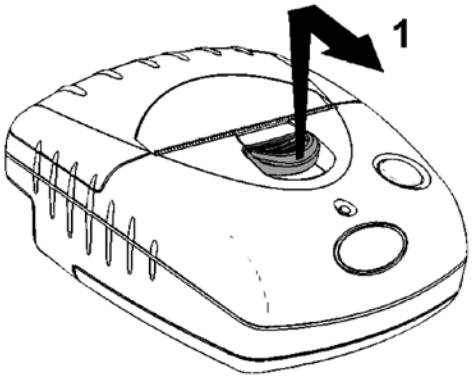
9.5.e **Red** - Low battery or other problem

9.5.f **No light** - Unit is in sleep mode, has a flat battery, or the battery is not connected

9.6 Paper

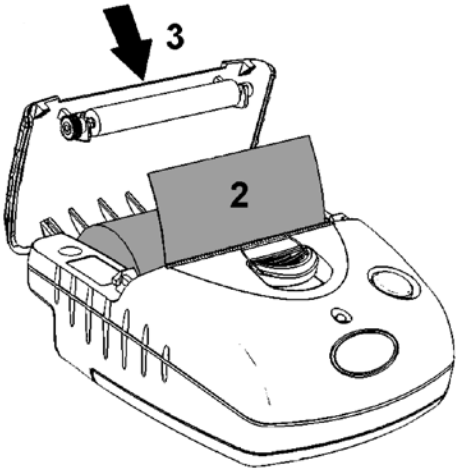
9.6.a When the printer is switched on, the button provides a paper feed function. A double press of the button will initiate a test print.

9.6.b The printer is supplied with spare paper rolls. To change the printer roll, pull the lid release catch (1) forwards with your thumb and the paper roll lid will spring open.



9.6.c Unwind a small amount of paper from the roll. Insert the new roll (2) ensuring the paper will pass through the paper feed (3) and close the cover with a click.

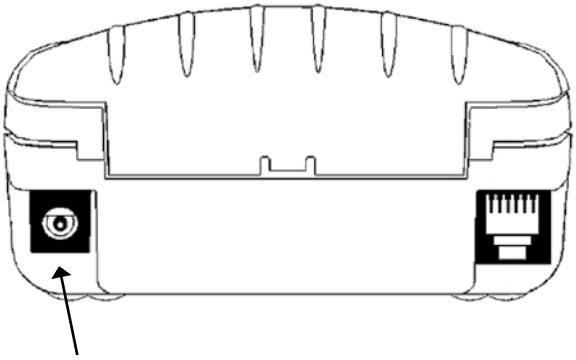
9.6.d After loading, check that the paper advances properly using the paper feed function, and tear off any excess by pulling the paper sharply towards you across the serrated tear bar. In the event of a jam or other paper loading problem, release the lid and straighten the paper before closing again.



9.6.e Self-adhesive paper rolls are also available and may be used in the same way as standard paper, but can be stuck to your patient records.

9.7 Charging the printer

9.7.a To charge the printer, plug the charger into a mains outlet socket and insert the charger jack plug into the rear of the printer. The light on the printer will flash green/orange to show the printer is on charge. The red charger light will also illuminate. A full charge will take approximately 15 hours.



Charger jack plug socket

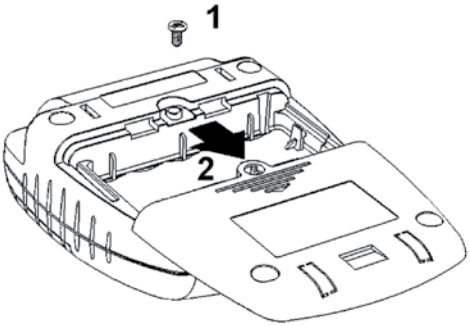
9.7.b The printer can be used as normal whilst charging.

9.7.c Once fully charged, the printer has enough power for around 10 hours standby use. The batteries should provide enough power to print several rolls of paper. The printer light will flash green/red when the batteries are low.

9.7.d **Note:**

The printer charger is not medically approved. The Otoport must not be in patient contact if connected to the printer whilst the printer is charging.

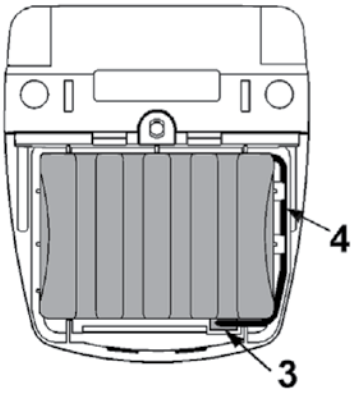
9.8 Changing the battery



9.8.a The printer battery will provide up to 500 charge and discharge cycles. If the battery performance deteriorates the batteries will need to be changed. A spare battery cradle, which takes 4 AAA batteries, is provided with the printer. Alternatively a new battery pack can be obtained from your dealer or Otodynamics.

9.8.b To change the battery pack:

9.8.c Remove the screw (1) from the battery compartment cover.



9.8.d Push down, and slide back the battery compartment cover (2).

9.8.e Remove the old battery pack and disconnect the battery pack connector, noting its orientation.

9.8.f Fit the battery pack connector (3) taking care to insert it correctly.

9.8.g Fit the battery pack ensuring wires (4) are not trapped.

9.8.h Slide back the battery compartment cover and replace the screw.

9.8.i

Important Note:

Only charge the printer if it contains an approved battery pack, supplied by your dealer or Otodynamics Ltd.

10 Scanning

10.1 Scanning facility

10.1.a As well as the standard data entry method using the keypad, the Otoport provides two optional methods for data entry using scanners. The scanning methods are designed to reduce testing session times by making the patient data entry method efficient.

10.1.b The scanners can also be used as part of the device security system during login. Each operator can be assigned a login card, which the Otoport will scan and verify in order to provide access to the machine.

10.2 Scanner types

10.2.a The Otoport has two scanning methods available.

10.2.1 Barcode scanning

10.2.1.a This method will scan barcodes which as standard hold numerical data. In screening programs which use barcode identification for patient ID, the Otoport can be used to scan this number quickly into the device.

10.2.1.b To scan with the barcode scanner, position the Otoport parallel with the barcode at a distance of around 10cm and select **Scan**. Line up the red light across the barcode.

10.2.1.c The Otoport will show a **Scanning** screen.

10.2.1.d When the barcode is read successfully a beep will sound and the barcode number will populate the required field. Select **Cancel** to abort the scan.

10.2.2 RFID scanning

10.2.2.a This method scans radio frequency identification (RFID) chips, which can hold enough alphanumeric data for a complete patient data record on the Otoport.

10.2.2.b To scan with the RFID scanner, hold the card up to the Otoport scanning window. Select **Scan** and swipe the Otoport across the card slowly. The Otoport will show a Scanning screen as above.

10.2.2.c When the RFID card is read successfully a beep will sound and data will populate the required fields. Select **Cancel** to abort the scan.

10.3 When to use the scanners

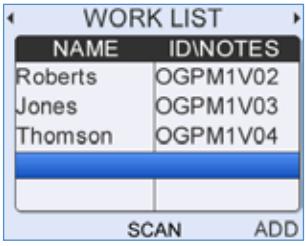
10.3.1 Entering patient details

10.3.1.a If a scan option is fitted, patient details may be entered using the **Scan** facility. To access the **Scan** function, first press any key (except the menu selection keys). The central menu option will now change to **Scan**.

Select **Scan** to populate the patient details. Make further edits manually with the keypad.

10.3.1.b Then continue to either test or save the result as normal.

10.3.2 Adding a patient to the Worklist



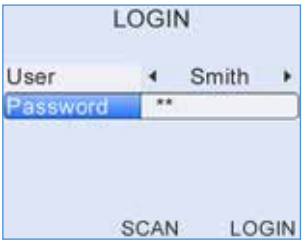
10.3.2.a If the Worklist already contains patients, scroll down to the last line, which will be empty, then select **Scan**. When the scanned details have been entered, you may make further edits manually with the keypad.

10.3.2.b Then continue to either test or save the result as normal.

10.3.3 At login

10.3.3.a In order for a user to login using the scanning method it is necessary to set-up their login account in the **Users** area (see chapter 8 **Configuration** for more details). On the **New user** screen, select **Scan**. The RFID method can set all user parameters. For barcode scanning, the user name, ID and password are automatically set, but the other user parameters need to be set manually.

10.3.3.b To login using a scanner, select **Scan** on the login screen.



10.3.3.c The Otoport will automatically login the user selected with their appropriate access rights and present the main menu.

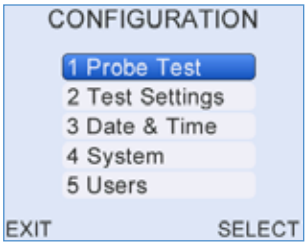
11 Probe checks

11.0.a Damage or malfunction of the Otoport or the probe can lead to errors in OAE recording. To ensure that any faults are detected before they lead to faulty data collection, the following tests can be performed.

11.0.b Probe checks should be carried out on a weekly basis.

11.0.c There are four different probe checks, described below. The Probe Test is initiated from within the **Configuration** menu; the Cavity, Occlusion and Real Ear tests involve running a standard TEOAE or DPOAE test.

11.1 Probe test



11.1.a **Probe Test** is an option accessed from the configuration menu (see chapter 8 **Configuration**).

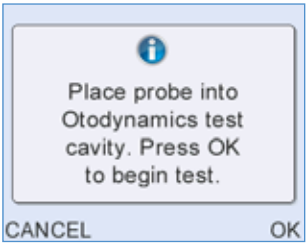
11.1.b A **Probe Test** should be performed regularly to monitor the calibration of the probe's output stimulus level and microphone response.

11.1.c Note:

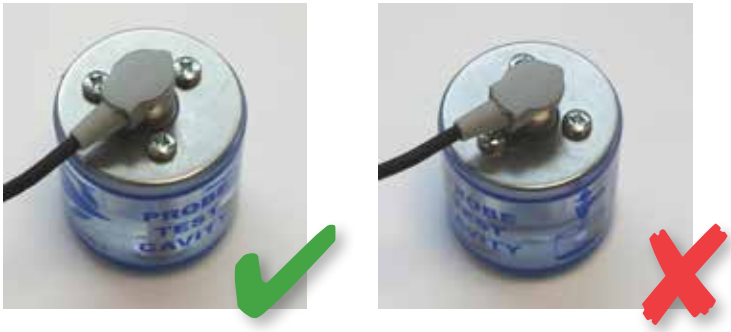
Probes supplied with a new Otocheck system are tested with the system and Probe Test levels are stored. These levels form a baseline to compare future tests against in order to monitor any calibration drift. It is not necessary to save a new baseline level for these probes.

Replacement probes supplied should be tested with your Otocheck system and new Probe Test results saved as a baseline reference (see 11.1.1.k below).

11.1.d On selection of **Probe Test** the message **Place Probe into Otodynamics Test Cavity. Press OK to begin test.** will be displayed.



11.1.e Remove the tip from the probe and place the cavity on a flat surface. Insert the probe into the test cavity at a 90 degree angle to the top of the cavity, between the screws, as shown below left. Press the probe firmly into the cavity until the shoulder of the probe touches the top of the cavity. When released, the probe will rise a little to its natural position and the shoulder may no longer touch the cavity. Inserting the probe at the wrong angle or with the probe head over one of the screws may result in incorrect test results.



11.1.f Select **OK** to begin the **Probe Test** or **Cancel** to return to the **Probe Menu** screen.

11.1.g The probe outputs sound at 1, 2 and 4kHz via its loud speaker(s). There is one loud speaker in the UGS (TEOAE) probe and two in the UGD (DPOAE) probe. The Otoport compares the response at each frequency against an absolute range and probe specific values stored on the probe connected.

11.1.h Checking the probe response against the absolute range determines if the probe is OK for use. Checking the probe response against the probe specific values is more sensitive and provides a warning if the response of the probe has changed.

11.1.1 Results

11.1.1.a The possible results of the test are:

11.1.1.b Pass

11.1.1.c The levels recorded at all frequencies are within the absolute range and within ± 3dB of the probe specific values.

11.1.1.d Fail

11.1.1.e One or more of the levels recorded are outside the absolute range specified for the probe. If a Fail is shown on screen inspect the probe coupler tubes for debris, replace the coupler if necessary and repeat the Probe Test, by selecting **Retest**, ensuring the ear piece is firmly inserted in the test cavity. If the test continues to fail there may be a fault with the probe or system. Contact your dealer or Otodynamics for advice.

11.1.1.f

Query

11.1.1.g The levels recorded at all frequencies are with the absolute range but one or more frequencies is more than ± 3 dB of the probe specific values. If a Query is shown inspect the probe coupler tubes for debris, replace the coupler if necessary and repeat the Probe Test by selecting **Retest**, ensuring the ear piece is firmly inserted in the test cavity. A Query result indicates that there have been changes in the probe but that these changes are not large enough to invalidate testing. It may be possible for the probe calibration to be adjusted if the probe is returned to Otodynamics.

11.1.1.h

Noisy

11.1.1.i There was significant noise during the calibration test. This noise may have influence the levels recorded so a **Retest** should be performed.

11.1.1.j Select **Back** to exit the probe test and return to the Probe Menu screen.

11.1.1.k Details

11.1.1.l The full test result can be viewed by selecting **Details**. The details screen shows the levels recorded from the probe loud speaker at each frequency tested. The NEW column shows the levels just recorded and the OLD results are the levels that are stored in the probe.

11.1.1.m Results are given for each frequency tested:

Pass –Tick/Check mark (✔) – The **NEW** and **OLD (**Stored) data for each of the two channels are within ± 3dB and are within the absolute limits.

Query - Question mark (?) Values differ by more than ± 3dB. The NEW and OLD levels are highlighted.

Fail – Cross (X) Values are outside the absolute range. The NEW level only is highlighted.

11.1.1.n The 1, 2 and 4kHz values may not be stored in the probe if a new probe is being used with the system. To save new data, run a Probe Test, record the values for each frequency and repeat by selecting **Retest.** Check that the values from two sequential tests are within ± 0.5dB before selecting **Save**.

11.1.1.o **Save** is only available to admin users. It is not available if the test was noisy or if the levels were outside the absolute range.

11.1.1.p On selecting **Save**, the screen title **Overwrite Stored?** will be shown highlighted. Select **Yes** to save the new data or **No** to keep the current stored values which may be blank for a newly registered probe. Before entering Probe Test the user will be prompted to register the probe with the Otoport.

11.1.1.q Select **Back** to exit the **Probe Test** screen and return to the **Configuration** screen.

11.2 Cavity test

11.2.a Due to mechanical or electrical failure or a faulty probe, the system may itself produce signals during a test that have similar characteristics to an OAE response. The test cavity will not produce any OAE signal so any signal produced in the cavity is the result of a fault.

11.2.b By performing an OAE test in a cavity rather than an ear it is possible to determine whether signal responses recorded in the ear are being generated by a fault.

11.2.c Before starting a cavity test: for the TE model, change the **Test Settings Display** to **Circles**; for the DP model, change the stimulus level to 65/55 (see chapter 8 **Configuration**).

11.2.d Follow the instructions on the previous page for inserting the probe into the test cavity.

11.2.e Start a test on the Otoport as you would for an ordinary ear (see chapter 5 **Test**).

11.2.f Follow the **Checkfit** and **Test** screen sequences until the test stops. In a cavity the Checkfit screen should indicate a large cavity volume.

11.2.g If the result **No Valid OAE** is displayed and the **Circles** are no more than 25 percent full when the test stops, the cavity test has passed.

11.2.h If the result **Stopped Too Soon**, **Too Noisy** or **Poor Probe Fit** is achieved, retest checking that the probe ear piece is firmly inserted into the test cavity and that the noise conditions within the room are acceptable for a test to be conducted. Continue to retest until either **No Valid OAE** or **Pass** result is given.

11.2.i If **Pass** is shown at the end of the test or if the circle for any band is more than ¼ filled, save and retest making sure the ear piece has been firmly pressed into the test cavity.

11.2.j Check the top of the test cavity and ensure it is securely attached to the clear plastic part of the test cavity. If the resources are available, repeat the test with a different test cavity and then with a different probe. This will identify which component is responsible for the problem. Contact your dealer or Otodynamics for further advice.

11.2.k **Note:**

If a signal is detected in the test cavity, ensure that five successful cavity tests are performed on the Otoport before returning it to use. Refit the probe in the cavity between each test.

11.3 Occlusion test

11.3.a If the probe coupler is not fitted correctly, sound may leak between the probe loudspeaker and microphone. The **Occlusion Test** helps to check that the probe is assembled and is performing correctly.

11.3.b To occlude the probe place a finger firmly over the end of the coupler tubes to block sound from being omitted from the ear piece and to prevent ambient noise from being read by the microphone. Then start a test as normal.

11.3.c All the cavity size indicators in **Checkfit** should be filled, indicating a very low sound level and **Check probe fit** should be displayed.

11.3.d If so, the **Occlusion Test** has passed.

11.3.e If not, check that the coupler is fitted to the probe correctly, making sure the coupler tube ends are fully occluded by a finger and that the environmental noise level is low. It may be necessary to change the coupler tubes. Repeat the test if necessary.

11.4 Real ear test

11.4.a Testing with a known good ear allows for test data to be checked for reproducibility.

11.4.b Before starting a real ear test, change the **Test Settings Display** to **Circles** (see chapter 8 **Configuration**). This will help when comparing results for reproducibility.

11.4.c A test may then be performed using the standard test procedure on the known good ear. This result may then be compared with previous results from the same ear. Real ear tests should be performed in similar test environments to be comparable.

11.4.d Some adult ears with no significant hearing loss produce little or no TEOAE. If possible the Real Ear Test should be performed on an ear which is known to have strong TEOAEs.

11.4.e If you are unable to achieve a **Real Ear OK** result in an ear which is known to have OAEs then:

- Check the subject has no middle or outer ear problems, such as a cold or wax blockage, which might prevent OAE recording.
- Check a good probe fit has been achieved.
- Check that the probe is not blocked.
- Check the probe still passes the probe calibration test (see above).
- Try recording emissions from another subject.

11.4.f If you are still unable to achieve a **Real Ear OK** result then, if the resources are available try recording with a different probe or with a different Otoport. If the problem persists, contact your dealer or Otodynamics.

12 Probe, tips and accessories

12.1 Probe and service accessories

12.1.a Your kit will include either a TEOAE or DPOAE probe, with appropriate accessories and sample probe tips, depending on the Otoport model purchased.

12.1.b **UGS TEOAE probe** (red) or **UGD DPOAE probe** (grey) with screw locking connector (see 2.8 **Connecting the probe**).

12.1.c **TPC Coupler Tubes** for UGS probe or **DPC** or UGD. See chapter 13 **Probe care** for information on changing coupler tubes.

12.1.d **BGS Body & Lid** for UGS probe or **BGD Body & Lid** for UGD probe.

12.2 Probe cable clip

12.2.a The probe cable clip is provided to aid the practical aspects of positioning and securing the probe cable during OAE testing. Using the probe cable clip can improve your test times by reducing noise from cable rub and providing greater probe stability.

12.2.1 Using the cable clip

12.2.1.a Push the plunger to open the cable grip.

12.2.1.b Place the probe cable in the slot and release the plunger. The position of the clip on the cable can be adjusted if necessary.

12.2.1.c Open the crocodile clothing clip.

12.2.1.d Attach the probe cable clip to the patient's clothing.

12.2.1.e If the cable slips through the grip, turn the head to grip the cable.

12.2.1.f Use a sterile wipe to clean the clip.

12.3 Probe tips

12.3.a Samples of either TEOAE or DPOAE tips are provided with your instrument. Further supplies may be obtained from your distributor or from Otodynamics.

12.3.1 TEOAE tips

T3E
REF **A90-01-2-0**
Fits ~3mm ear canal
Small and premature newborns

T4.5C
REF **A90-02-2-0**
Fits ~4.5mm ear canal
Small newborns

T5C
REF **A90-20-2-0**
Fits ~5mm ear canal
Newborns

T5.5B
REF **A90-03-2-0**
Fits ~5.5mm ear canal
Most newborns

T6.5B
REF **A90-04-2-0**
Fits ~6.5mm ear canal
Large newborns and first year infants

T7M
REF **A90-24-2-0**
Fits ~7mm ear canal
Infants and children

T8M
REF **A90-05-2-0**
Fits ~8mm ear canal
Infants and small adult ears

T9M
REF **A90-06-2-0**
Fits ~9mm ear canal
Most adult ears

T11M
REF **A90-07-2-0**
Fits ~11mm ear canal
Large adult ears

T13M
REF **A90-18-2-0**
Fits ~13mm ear canal
Extra large adult ears

12.3.2 DPOAE+TEOAE tips

R4.8S
REF **A90-08-2-0**
Fits ~4.8mm ear canal
Small newborns

R5.8B
REF **A90-16-2-0**
Fits ~5.8mm ear canal
Most newborns

R6.8B
REF **A90-17-2-0**
Fits ~6.8mm ear canal
Large newborns and first year infants

R7M
REF **A90-25-2-0**
Fits ~7mm ear canal
Infants and children

R8M
REF **A90-09-2-0**
Fits ~8mm ear canal
Infants and small adult ears

R9M
REF **A90-10-2-0**
Fits ~9mm ear canal
Most adult ears

R11M
REF **A90-11-2-0**
Fits ~11mm ear canal
Large adult ears

R13M
REF **A90-19-2-0**
Fits ~13mm ear canal
Extra large adult ears

12.3.3 Use of tips

12.3.3.a All Otodynamics probe tips are disposable and MUST be discarded after each test. The probe coupler tubes should be visually examined for signs of contamination and the outer parts cleaned with an antiseptic wipe. Take care not to squeeze any cleaning fluid into the tubes.

12.3.3.b The TEOAE tip design leaves a ~0.5mm gap between the end of the coupler tubes and the end of the tip. Therefore, the tubes should never come into contact with the patient.

12.3.3.c OAEs should NOT be conducted if there is evidence of fluid of any kind in the ear canal. Not only does this pose a contamination risk, but OAEs cannot be recorded through fluid.

12.3.3.d In the event of an accident with body fluids, the tip, coupler tubes and probe body must be changed.

13 Probe care

13.1 Cleaning

13.1.a The following is the suggested method of cleaning an Otodynamics probe. It should be noted that the probe is a precision assembly and, as such, care should be taken throughout in its handling and cleaning.

13.1.b **Cable -** The cable may be cleaned with antiseptic fluid or wipes.

13.1.c **Probe casing -** The probe casing may be cleaned using antiseptic wipes and dried with a tissue immediately afterwards. Do not allow liquids to enter the sound tubes.

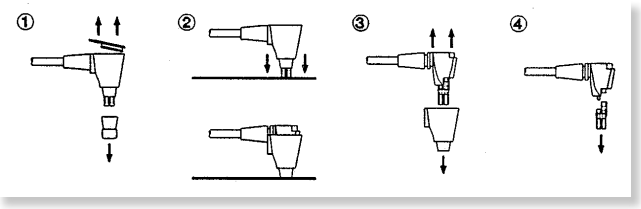
13.1.d **Coupler assembly -** Each coupler assembly has two sound tubes. These are protected from ingress of foreign materials by wax guards in the tubes and by the disposable probe tip. There is a loudspeaker at the end of one tube and a microphone at the end of the other. Cleaning solution must not penetrate the tubes.

13.2 Changing probe coupler tubes

13.2.a The probe has sound tubes combined into a single coupler assembly that can easily be replaced at regular intervals or when contaminated.

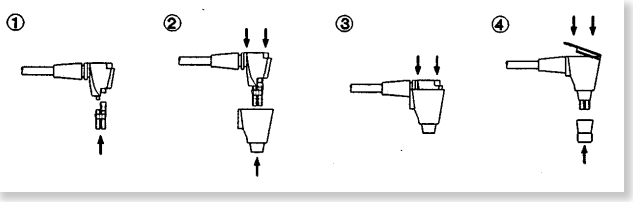
13.2.1 Disassembling the probe

13.2.1.a First, unplug the probe from the instrument. Remove the tip and then the lid (fig. 1). Remove the coupler tubes by pushing the end of the tubes down onto a hard surface (fig. 2). Pull out the tubes by gripping them (fig. 3). Never remove them by pulling on the cable. Finally, pull the coupler tubes away from the probe (fig. 4).



13.2.2 Reassembling the probe

13.2.2.a Fit the new coupler tubes to the probe assembly (fig. 1). Fit the outer shell (figs. 2 and 3), followed by the lid (fig. 4). Click the lid into place using firm finger pressure only. Finally, fit a new tip (fig. 4).



13.2.3 Notes:

- Fit a new tip for each test.
- Check that the coupler tubes are not contaminated before fitting the tip.
- If the coupler tubes are contaminated, **replace them**. We recommend fitting new coupler tubes at regular intervals (approx every 20-40 tests) as a preventive measure.
- Perform weekly probe QA tests (see chapter 11 **Probe tests**).

13.3 Probes safety note

13.3.a Probes are designed for use with an Otodynamics disposable tip. Use of a tip is essential.

13.3.b Use without a tip will expose the ear canal to the hard plastic sound tubes and this **might cause injury**.

13.3.c Use without a tip or with an incorrect or non-Otodynamics tip may also cause serious errors in measurement. This could invalidate the OAE recording.

14 Care of the Otoport Lite

14.0.a The Otoport is robustly constructed but is a precision instrument, so should be handled with care. Be careful when connecting the probe, charger, PC cable or printer cable.

14.0.b
- Do not drop the Otoport
- Do not leave in strong sunlight
- Do not expose to high temperatures
- Do not touch the connector socket pins by hand
- Do not force the connection of the probe or charger/PC cable/printer cable

14.1 Use of the Otoport and cleaning

14.1.a The following is a suggested cleaning method for the Otoport and probe. The Otoport and accessories are precision assemblies, so care should be taken throughout handling and cleaning.

14.1.b Other than the probe ear piece and cable, the Otoport hardware should not come into contact with the patient being tested. Otodynamics probe tips are disposable and for single use only. A new tip should be used for each ear tested. The tip protrudes ~ 0.5mm beyond the end of the probe coupler, to prevent contact of the sound tubes with the patient.

14.1.c Between patients, wipe the probe ear piece and cable with an alcohol based sterile wipe or cloth and antiseptic fluid. Dry the assembly with tissue immediately afterwards and do not let liquid pass down the coupler sound tubes. The probe ear piece is serviceable and its body, lid and coupler tubes can be replaced. The coupler tubes should be replaced weekly or after 20-40 tests, or if they have been contaminated. The body and lid should be replaced if contaminated. Visually check the ear piece for signs of dirt before each test.

14.1.d Before fitting each tip, ensure the sound tubes are carefully examined for any sign of debris that may have entered them. Replace any part of the probe ear piece as necessary. (See chapter 13 **Probe care** for details)

14.1.e Ensure your hands are cleaned thoroughly between each patient tested.

14.1.f Clean the Otoport each day before a testing session, or according to local requirements. Ensure the Otoport is cleaned if it becomes contaminated. Clean surfaces of the Otoport with an alcohol based sterile wipe or cloth and antiseptic fluid. Dry the Otoport with tissue immediately afterwards. Do not allow liquid to enter the instrument and do not immerse in fluid. Do not allow liquid to come into contact with the connection sockets. Do no poke any materials into either the probe or charger/pc cable sockets.

14.1.g If additional hygienic protection is required, use the Otoport in an infection control sleeve. This can also be cleaned with a sterile wipe or cloth with antiseptic fluid. The sleeves are disposable, so should be replaced weekly or after approximately every 50 tests.

15 Otoport Lite power

15.0.a **Important Note:**

Only charge your Otoport with the charger, charging cradle, or docking station supplied by Otodynamics

15.1 Battery life

15.1.a The Otoport is powered using an internal rechargeable battery. The battery will provide enough power for over 250 tests from a single charge. With built in power save functions and by switching the device off for the periods between tests, the battery will provide enough power for over a week's intensive use.

15.2 Initial charge

15.2.a The Otoport is fully charged before it leaves the Otodynamics factory. However, the battery will discharge slowly, even if the device is switched off. It is therefore recommended that an initial charge is provided to fully charge the battery before using your Otoport for the first time.

15.3 Standby

15.3.a To save power, the Otoport will go into standby mode after 3 minutes of inactivity. The standby screen will be displayed.

15.3.b The Otoport will not go into standby if a test is being performed.

15.3.c To resume from standby, press any key on the keypad. The Otoport will wake up and return to the previous screen displayed.

15.3.d If the Otoport is left for 20 minutes in standby it will turn off. An audible beep will be emitted from the device for a period of 10 seconds to alert the user prior to the automatic shut down.

15.3.e Notes:

Following an OAE recording, always save test data, as data that has not been saved prior to auto switch off will be lost.

Over time batteries will wear and lose their capacity, resulting in quicker discharge. The batteries may therefore need replacing around every 4 years of use.

15.4

Battery charge

15.4.a When the Otoport is switched on, the opening screen shows a battery indicator which displays the remaining level of battery charge.

15.4.b The indicator has 5 segments which convey the total Battery Charge remaining. The battery segments are shaded according to the following criteria.

Segments Displayed	Battery Power (%)
7	95 - 100
6	75 - 94
5	55 - 74
4	40 - 54
3	30 - 39
2	20 - 29
1	10 - 19
0	< 10

15.4.1 Low battery

15.4.1.a When the battery power reaches less than 10% remaining a **Low Battery** warning message will be displayed. This equates to approximately 30 minutes of testing time. Select **OK** to accept the message and return to the previous screen. This screen will continue to appear every minute, as a reminder to charge the battery.

15.4.2 Critical battery

15.4.2.a When the battery power reaches 7% remaining a **Critical Battery** warning message will appear on screen. This equates to approximately 10 minutes of use. Select **OK** to accept the message and return to the previous screen. It will not be possible to start a new test when the Otoport has reached this level of charge. The Otoport should be charged as soon as convenient.

15.4.3 Auto switch off

15.4.3.a The Otoport will automatically switch off when the battery is empty. It will be necessary to charge the Otoport before it will switch on again.

15.5 Charging the Otoport

15.5.a Observe the on-screen battery indicators to determine when to charge your Otoport. In general it is advisable to charge the Otoport batteries when the indicator is empty, showing less than 10% charge. However, the batteries should be at least 30% charged if a full day's testing is planned.

15.5.b It is recommended to charge the Otoport using the charger supplied, but it is also possible to charge the device using the PC cable connected to a PC.

15.5.c Note:

Do not charge more than one Otoport on the same PC at any one time.

15.5.1 Connecting the Otoport for charging

15.5.1.a Switch off the Otoport prior to charging.

15.5.1.b Connect the mains lead to the charger and plug the mains lead into a power socket and switch on the power. The green light on the charger will illuminate indicating it is powered.

15.5.1.c Then connect the slotted charger plug to the Otoport. Ensure the arrow is facing upwards.

15.5.1.d

Notes:

If forced it is possible to insert the charger connector into the Otoport the wrong way up. In this position the Otoport will not charge.

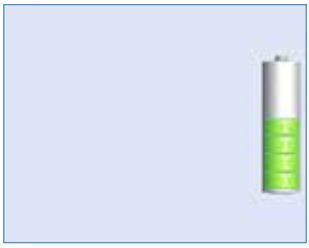
Disconnect the connector and re-insert with the arrow facing upwards.

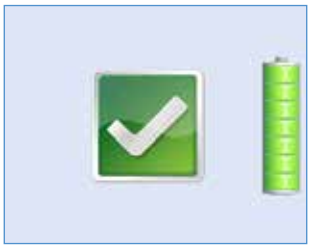
If the cables provided with your Otoport have a locking connector, as shown below, squeeze the release keys at the sides of the connector when removing the plug.

15.5.1.e When the Otoport is connected the display will show the current battery level. This screen is updated every minute to show how the charge is progressing.

15.5.1.f A full charge will take up to 4 ½ hours.

15.5.1.g When the device is fully charged a large tick will appear on the screen.





15.5.2 Additional charge indicators

15.5.2.a There are additional charge indicators on the side of the Otoport.

15.5.2.b • **Power light** - The green light below the plug symbol shows that the device is powered.

15.5.2.c • **Charging light** - The orange light below the battery symbol will illuminate when the device is being charged.

15.5.2.d Note:

> If the device appears fully charged, with a tick displayed on screen, but the charging light is still on, if convenient, allow the device to continue to charge until the charge light goes out.

15.5.2.e It is possible to leave the charger connected to the Otoport for extended periods, even if the device is fully charged. This may be convenient if you wish to leave the device charging overnight.

15.5.2.f When powered by either a charger or PC, the Otoport is powered from the attached device and not its internal batteries.

15.5.2.g When connected to a charger it is possible to switch on and control the Otoport but it is not possible to run a test.

15.5.2.h When connected to a PC it is not possible to control the Otoport. If the Otoport is on when it is connected to a PC the current screen displayed will remain until the device is unplugged again.

15.5.3 Disconnecting the Otoport

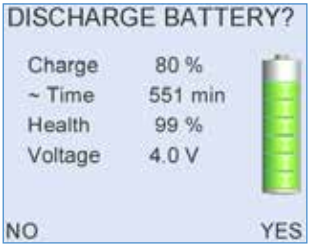
15.5.3.a When the charging cable is disconnected, the power light will extinguish on the Otoport and if the Otoport was off prior to the charging session, the screen will return to blank. If on during the charging session the current screen will remain displayed.

15.6 Conditioning the Otoport battery

15.6.a In order to maintain the Otoport battery and keep it at optimal performance you should condition the battery once per year, or if the unit's battery appears to run down more quickly than expected. This process involves completely discharging the battery, using a function provided in the Otoport **System** area and then fully charging the device (see chapter 8 **Configuration**).

15.6.b The condition utility is available from the **Configuration** menu by selecting **System** then **Battery**. Selecting **Condition** and confirming will set the device to full power to drain the battery.

15.6.c This process can take up to 6 hours. Select **Cancel** to stop the conditioning process. The Otoport will automatically switch off when the battery has been fully discharged. Now fully charge the Otoport to complete the battery condition cycle. Wait for the tick on the screen and for the charge light to extinguish, to confirm a full charge.



15.6.1 Additional battery care

15.6.1.a If the Otoport is not in regular use, in order to maintain the battery, fully charge the device every two months.

16 Troubleshooting

16.1 Otoport lock-up

16.1.a In the unlikely event of an Otoport lock-up and it is not possible to control the device, turn the unit off and switch it on again. If this is not possible, hold down the on/off power key for 10 seconds; this will force the unit to switch off. Turn on the Otoport again.

16.2 Switch on

16.2.a During switch on, the Otoport conducts a series of system checks. If the Otoport will not switch on and complete its start up sequence, check that it is charged and try again. If the Otoport still fails to complete its start up sequence then contact your dealer or Otodyamics for support.

16.3 System details

16.3.a The **Configuration** area includes in the **System** menu a **System details** screen.

16.3.b This screen provides information for Otodynamics engineers relating to the Otoport hardware. If your device is not functioning correctly or you suspect a fault, go to the **System details** menu and check for any error number reported at the top of the screen. If zeros are reported at the top of the screen, no errors have been detected on the device. For support regarding a fault, report error numbers to your dealer or Otodynamics.

16.3.c Select **Reset** to reset the Otoport to factory default settings. Changes from the default setting and any users or worklist patients added to the device will be lost. No test data will be removed.

16.3.d Select **Format** to reformat the Otoport database. Any records held on the device will be irrecoverably lost.

16.3.e The **Format** and **Reset** options are only available to users with Admin rights.

16.4 Instrument fault message

16.4.a In the event of an instrument fault, the following message will be displayed at the start a test.

16.4.b **Instrument fault, turn off Otoport then run system checks**.

16.4.c No stimulus will be delivered from the Otoport probe and you will not be able to start a test. Turn off the device and then switch it on again.

16.4.d ### Important Note:

> The **Instrument Fault** message can be triggered by a partially connected probe. Ensure that the probe is fully connected and the knurled sleeve screwed up correctly. (See **Connecting the probe** in the **Getting started** section).

16.4.e Run the probe checks (see chapter 11). If the tests are 'OK' the device is functioning correctly and can be used for OAE testing again.

16.4.f If you receive the **Instrument fault** message again, contact your dealer or Otodynamics for support.

16.5 Hardware fault messages

16.5.a The Otoport performs a series of hardware tests when it is first turned on. In the event of a fault being detected the following message will be displayed:

16.5.b The error code number displayed indicates the type of error detected. You should make a note of this error number. The Otoport should then be turned on and off a number of times to ensure that the error doesn't reoccur.

16.5.c If you receive the hardware fault message again, contact your distributor or Otodynamics for support.

16.5.d **Error 2**

16.5.e The above message indicates that excessive noise was detected during start up. The noise may have been detected through the probe, if it was connected. Noise detected through the probe does not indicate a fault. If this message is displayed, turn the unit off, disconnect the probe and then turn it back on. If the message is consistently displayed with the probe disconnected, then contact Otodynamics.

17 Training

17.0.a It is important that the operator of the Otoport is properly trained before using the instrument. The manual should be read before use and note taken of the sections marked with the training required symbol.

17.0.b Where the training symbol is directly beneath a chapter title, it indicates that training is required for everything within the chapter. Where the symbol appears beneath a section heading, it indicates that training is required for that section only.

17.0.c Training in the UK is provided by Otodynamics Ltd. Training elsewhere is via an approved dealer who has been trained by Otodynamics. Training on OAEs and use of the equipment may also be provided by previously trained staff and qualified audiologists.

17.0.d Ensure your local policy for infection control is followed, as well as reading the recommendations in this manual (see section 20.1 **Use of the Otoport and cleaning**).

17.0.e If a problem occurs during the operation of your Otoport or Otolink software or a message or warning appears that you don't understand, make note of the issue and messages provided. Refer these to your department lead, or directly to Otodynamics or your dealer for support.

18 Obtaining service

18.0.a Otodynamics or its authorised distributor will replace or service, free of charge, this Otoport for a period of 12 months from the date of purchase, where the fault is not associated with misuse. Servicing after that period will be provided at reasonable cost.

18.0.b Probes failing because of faulty construction will be replaced subject to inspection. Probes must be treated with care. Do not allow cleaning fluid to enter the sound tubes.

18.0.c When sending equipment to Otodynamics for service or repair, please ensure all items, particularly the OAE instrument and probe, are clean and free from contamination. Otodynamics cannot guarantee the equipment will be contamination free when returned to you and suggest that it is cleaned in accordance with your infection control protocols before being put back into use.

18.0.d Please contact your distributor or Otodynamics for advice before returning an item for repair. You will be asked for your instrument serial number, which can be found on the back on the Otoport.

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19 Calibration

19.0.a The Otoport is a precision instrument designed to make accurate measurements of OAE responses. Before it leaves Otodynamics, each system supplied is calibrated using high quality acoustic measuring equipment traceable to national standards.

19.0.b Users should conduct the recommended weekly checks (see chapter 11) to ensure the instrument is working correctly. In addition to this, the calibration of the instrument should be periodically checked with laboratory equipment. Otodynamics advises regular calibration checks at intervals not exceeding 3 years and ideally annually.

19.0.c Contact your dealer or Otodynamics to arrange a calibration check.

20 Mode of operation

20.1 TEOAE model

Parameter	Description
Stimulus	**Idle** 80µs positive broadband square wave pulse with an intensity of 64dB pe (peak equivalent) in a 1cc cavity. **Adjusted** 80µs positive broadband square wave. **Test** 300µs biphasic broadband triangular pulse.
Waveform sample rate	20kHz
Stimulus pattern	Each sweep presents 8 stimuli for each to the two response buffers (16 stimuli in total). The stimulus presentation pattern is: X X X Y -X -X -X -Y Where: Y = -3X
Response buffer averaging	The responses from each stimuli in a sweep are summed and averaged. Averaging this stimulus pattern removes artefacts which scale linearly leaving only the OAE signal which is non linear. These sub averages are alternately added to two separate averages. These separate averages are referred to as waveforms A and B.

Signal and noise calculation

Measures of signal and noise levels are based on the correlation and differences between waveforms A and B.

Stimulus repetition rate

One stimulus every 13ms, approximately 80 stims per second.

Response window

2.5-12.5 ms or 4-10ms after start of stimulus. Cosine filtered with rise and fall time of 2ms.

Response frequency bands

Half octave, centres at 1, 1.4, 2, 2.8 and 4kHz.

Response frequency range

841-4757Hz

Microphone input filter

1189-4757Hz

The attenuation at these frequencies is 3dB. Attenuation increases by 80dB/decade below and 40dB/decade above these frequencies.

Memory capacity

Patients	500
Tests per patient	256
Total tests	500

20.2 DPOAE model

Parameter	Description
Checkfit stimulus	80µs positive broadband square wave pulse with an intensity of 64dB pe (peak equivalent) in a 1cc cavity.
Sample rate	25.6kHz
Sample buffer	80ms (gives 2048 points)
FFT frequency bin	25Hz
DP Noise calculation	DP noise from the five spectral points above and the five points below the DP frequency. In the 'Rapid' noise mode, the mean of these points gives the noise level. In the 'Standard' noise mode the mean of these points plus two standard deviations gives the noise level.
Noise rejection calculation	The noise level for noise reject is calculated from the difference between consecutive 80ms samples.
Stimulus frequencies (F2)	Sine waves of 6, 4, 3 and 2 kHz
Frequency ratio	F2 = 1.22 F1
Memory capacity	**Patients** 500 **Tests per patient** 256 **Total tests** 500

21 Technical specifications

21.1 General

Note:

The Otoport has no user serviceable parts. Any required servicing must be conducted by Otodynamics Ltd or authorised service facilities only

21.1.1 Physical

Hand-held device:	197mm x 70mm(max) x 30mm Weight 0.55lbs (250g)
Charger:	90mm x 38mm x 28mm – Weight 120g

21.1.2 Interfaces

Probe connector compatible with Otodynamics UGx probes (8 pin)
Charging/Data connector - connects to Otodynamics PSU (charging) or to PC USB port (USB 1.1or 2.0) via Data Cable
Bluetooth wireless print (option)
RFID reader (option)

21.1.3 Indicators

Data Display:	Resolution: QVGA (320 x 240 pixels), 166 dpi Technology: Colour LCD, 16 bit (displaying 65K colours) Viewable Area: 46.5mm x 36.5mm
Backlight:	White - intelligent control
Probe fit:	Noise OK: Blue LED (‘N’) Stimulus OK: Blue LED (‘S’)
Power/Charge:	Power OK: Green LED Fast charge: Amber LED
Audible:	Wide range speaker provides audio feedback of status

21.1.4 Keypad

19 key alphanumeric with cursor control and soft keys

21.1.5 Clock/Calendar

Internal Real Time Clock/Calendar operates to 2099

21.1.6 Power

Li-Polymer Battery
Intelligent multi-level power control for charging/testing/idle/sleep/shutdown:
After 1.5 minutes unit will enter sleep mode
After 20 minutes in sleep mode unit will shut down

Sleep time:	20 hours minimum (with fully charged battery)
Running time:	6 hours minimum (continuous data collection)
Battery voltage operating range:	3-4.2V
Max consumption when testing:	720mW
Max consumption when charging:	2.5W
Source:	1000mAh lithium polymer internal rechargeable cells
Charge time:	3 hours to 90% capacity Approximately 4 hours to 100%

21.1.7 Hardware Options

Bluetooth wireless printing
Barcode scanner
RFID reader

21.1.8 Hardware processing and storage

Embedded microcontroller plus dedicated hardware DSP engine
4GB of non-volatile memory for storing programs, configuration, patient details and test results

21.1.9 Analogue performance

Output channels:	2 x 16bit resolution
Input channels:	1 x 16bit resolution
Sample rate:	Variable
Frequency response:	Electrical – 160Hz to 12KHz

21.1.10 Environmental

Protect from heat and radioactive sources

Keep dry

Transport and storage:

Temperature range: 0 to 40 Celsius

Pressure: 23KPa to 101KPa

Humidity: 10% to 90% non-condensing

Warm-up time: <10s when unit is stored within stated temperature range

Operating: Indoor use

Temperature range: 5 to 40 Celsius

Humidity: Max 80% up to 31C decreasing linearly to 5% RH at 40C

Otodynamics instruments and probes are calibrated at an ambient pressure of 101 kPa (standard atmospheric pressure at sea level). Lowering the ambient pressure significantly (e.g. when operating at altitude) alters the acoustic response of the probe. For instance, at an ambient pressure of 80 kPa (standard atmospheric pressure at 2000m) changes of up to 2 dB can be observed in the response of the probe around 2KHz. This could cause the probe to fail standard calibration tests.

21.1.11 Classifications and standards

Device Class 2a	(Directive 93/42/EEC)
BS EN ISO 13485:2003	(REF: EN46001 superseded 01/03/2004)
ISO 14971:	Application of risk management
BS EN 60601-1:	Medical Electrical Equipment Part 1: General Requirements for Safety
BS EN 60601-1-1:	Medical Electrical Equipment - Part 1: General Requirements for Safety - Collateral Standard - Safety Requirements for Medical Electrical Systems
BS EN 60601-1-2:	Medical Electrical Equipment - Part 1-2: General Requirements for Safety - Collateral Standard: Electromagnetic Compatibility
BS EN 60601-1-4:	Medical electrical equipment - Part 1 General requirements for safety. Section 4 Collateral standard, programmable electrical medical systems
UL 60601-1:	Medical Electrical Equipment, Part 1: General Requirements for Safety
CSA-C22.601:	Medical Electrical Equipment

21.2

Electromagnetic Compatibility

The Otoport should be put into service according to the EMC (Electromagnetic Compatibility) information provided here.

Portable and mobile RF (Radio Frequency) communications equipment can affect the operation of the Otoport. In particular, mobile telephones ('cellphones') should not be operated within 3.3m of the Otoport.

The use of probes, chargers and connection cables other than those supplied by Otodynamics Ltd, and specifically for use with the Otoport may result in increased emissions or decreased immunity of the Otoport.

Guidance and manufacturer's declaration – electromagnetic emissions

The Otoport is intended for use in the electromagnetic environment specified below. The user of the Otoport should ensure that it is used in such an environment.

Emissions test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1	The Otoport uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby equipment.
RF emissions CISPR 11	Class B	The Otoport is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	

The Otoport should not be used adjacent to or stacked with other equipment and that if adjacent or stacked use is necessary the Otoport should be observed to verify normal operation in the configuration in which it is used.

Guidance and manufacturer's declaration – electromagnetic immunity

The Otoport is intended for use in the electromagnetic environment specified below. The user of the Otoport should ensure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Electrostatic discharge (ESD) IEC 61000-4-2	± 6 kV contact ± 8 kV air	± 6kV contact ± 8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	± 2 kV for power supply lines ±1 kV for input/ output lines	± 2kV for power supply lines ±1kV for input/ output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth	± 1kV differential mode ± 2kV common mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interrup-tions and voltage variations on power supply input lines IEC 61000-4-11	<5% U_T (>95% dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles <5% U_T (>95% dip in U_T) for 5 s	<5% U_T (>95% dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles <5% U_T (>95% dip in U_T) for 5 s	Mains power quality should be that of a typical commercial or hospital environment. If the user of the Otoport requires continued operation during power mains interruptions, it is recommended that the Otoport be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

NOTE U_T is the a.c. mains voltage prior to application of the test level.

The following functions of the Otoport are deemed ‘essential performance’ and were tested for immunity in compliance with IEC60601-1-2:

(a) The collection of Otoacoustic Emissions (OAEs)
(b) The retention of user settings and test results

Guidance and manufacturer's declaration – electromagnetic immunity

The Otoport is intended for use in the electromagnetic environment specified below. The customer or the user of the Otoport should ensure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
			Portable and mobile RF communications equipment should be used no closer to any part of the Otoport including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance**
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 Vrms	$d = 1.2\sqrt{P}$
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	$d = 1.2\sqrt{P}$ 80 MHz to 800 MHz $d = 2.3\sqrt{P}$ 800 MHz to 2.5 GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and *d* is the recommended separation distance in metres (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,[a] should be less than the compliance level in each frequency range.[b] Interference may occur in the vicinity of equipment marked with the following symbol:

Notes:

1 At 80 MHz and 800 MHz, the higher frequency range applies.

2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

(a) Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the Otoport is used exceeds the applicable RF compliance level above, the Otoport should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the Otoport.

(b) Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Recommended separation distances between portable and mobile RF communications equipment and the Otoport

The Otoport is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The user of the Otoport can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Otoport as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter (W)	Separation distance according to frequency of transmitter (m)		
	150 kHz to 80 MHz $d = 1.2\sqrt{P}$	80 MHz to 800 MHz $d = 1.2\sqrt{P}$	800 MHz to 2.5 GHz $d = 2.3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in metres (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

Notes:

1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

The Otoport can be optionally configured with either/both Bluetooth and RFID functions. The frequency bands for reception and transmission of RF energy for these functions are as follows:

(a) Bluetooth – 2.4GHz to 2.4835GHz
(b) RFID – 13.56MHz

The Bluetooth and RFID functions of the Otoport may be interfered with by other equipment, even if that equipment complies with CISPR emission requirements.

21.3 EN60645-3 conformance notes

These notes are provided in compliance with EN60645-3 “Electroacoustics audiometric equipment - Part 3: test signals of short duration.”

(a) Types of short duration stimuli:

The Otoport TEOAE test uses short duration stimuli. During test setup a ‘rectangular stimulus’ is used. During data collection a ‘bipolar stimulus’ is used. The rectangular is a unipolar pulse of 78uS length. The bipolar stimulus is 1 cycle of a triangle waveform of 240uS period. Both stimuli are low pass filtered by a 10kHz anti-alias filter, which ‘rounds’ any ‘sharp edges’.

(b) Transducers and headband force:

The stimulus is delivered to the patient’s ear using a UGS or UGD Otodynamics probe. The probe tip holds the probe ear piece in the ear canal, with no headband or other retaining device required.

(c) Sound field system:

The sound field is generated by the probe sealed in the ear canal by its tip.

(d & e) Calibration cavity and measurement type:

For the purposes of EN60645-3 calibration was performed in an occluded ear canal simulator conforming to IEC 60711 (Bruel and Kjear type 4157). The probe was mounted in a DB2012 adaptor using an Otodynamics probe tip. The sound ports of the probe were aligned with the 4157 reference plane. A UGD probe was used for the calibration. Sound levels from the 4157 ear simulator were measured in dB SPL peak-to-peak equivalent, as defined in EN60645-3.

(f) Signal levels:

The following conversion factors convert between the stimulus level reported on the Otoport screen and the signal level in the IEC 60711 occluded ear simulator:

rectangular stimulus: -6.1dB
bipolar stimulus: -7.1dB

The following conversion factors convert between the signal level generated in the ear simulator by the Otoport stimulus and the level that would be generated by a ‘reference stimulus’ of the same peak to peak electrical drive. (The ‘reference stimulus is a 100uS unipolar rectangular pulse, as defined in EN60645-3.):

rectangular stimulus: +3.0dB
bipolar stimulus: +2.4dB

Suppose, for example, that a stimulus level of 90dB is reported by the Otoport during stimulus setup (rectangular stimulus). If this stimulus was replaced by the reference stimulus, of the same amplitude, the level generated in a IEC 60711 ear simulator would be:

90dB + -6.1dB + 3.0dB = 86.9 dB SPL peak-to-peak equivalent.

(g) Polarity of stimulus:

The polarity of the stimulus varies between positive and negative, according to the TEOAE test sequence.

(h) Repetition rate:

The stimulus is repeated every 12.5mS during standard Otoport TEOAE setup and testing.

(i) Covered in (a) above

(j) Covered in (f) above

21.4 Symbol explanations

	Class II
	Type BF
	Caution
	USB 1.1
	When discarded, the item must be sent to separate collection facilities for recovery and recycling
	Probe socket
	Battery charging indicator
	Power supply connection
S	Stimulus OK indicator
N	Noise OK indicator
	Refer to operating instructions
	Training required

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